

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
5 August 2004 (05.08.2004)

PCT

(10) International Publication Number  
WO 2004/064647 A1

(51) International Patent Classification<sup>7</sup>: A61B 17/02

(21) International Application Number:  
PCT/US2004/000597

(22) International Filing Date: 9 January 2004 (09.01.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
10/342,932 15 January 2003 (15.01.2003) US

(71) Applicant: MEDTRONIC, INC. [US/US]; MS LC340,  
710 Medtronic Parkway NE, Minneapolis, MN 55432  
(US).

(72) Inventors: BONNER, Matthew, D.; 18400 5th Avenue  
North, Plymouth, MN 55447 (US). PIGNATO, Paul, A.;  
8440 North Fawn Lake Road, Northeast, Stacy, MN 55079  
(US). JAHNS, Scott, E.; 923 3rd Street, Hudson, WI  
54016 (US). USHER, Raymond, W.; 199 120th Avenue  
Northwest, Coon Rapids, MN 55448 (US).

(74) Agents: LATHAM, Daniel, W. et al.; MC LC340, 710  
Medtronic Parkway, Minneapolis, MN 55432 (US).

(81) Designated States (unless otherwise indicated, for every  
kind of national protection available): AE, AG, AL, AM,  
AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,

CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,  
GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,  
KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD,  
MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG,  
PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM,  
TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM,  
ZW.

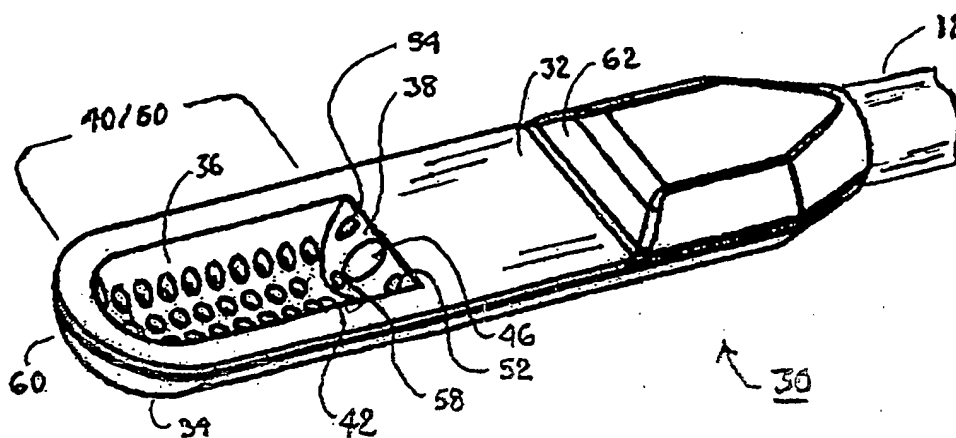
(84) Designated States (unless otherwise indicated, for every  
kind of regional protection available): ARIPO (BW, GH,  
GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),  
Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), Euro-  
pean (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR,  
GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK,  
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,  
ML, MR, NE, SN, TD, TG).

**Declaration under Rule 4.17:**

— as to applicant's entitlement to apply for and be granted  
a patent (Rule 4.17(ii)) for the following designations AE,  
AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ,  
CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE,  
EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS,  
JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA,  
MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM,  
PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ,  
TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM,  
ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD,

[Continued on next page]

(54) Title: METHODS AND APPARATUS FOR ACCESSING AND STABILIZING AN AREA OF THE HEART



(57) Abstract: A tubular suction tool (10) for accessing an anatomic surface or anatomic space and particularly the pericardium to access pericardial space and the epicardial surface of the heart to implant cardiac leads (90) in a minimally invasive manner are disclosed. The suction tool incorporates a suction pad (30) concave wall defining a suction cavity, a plurality of suction ports (42) arrayed about the concave wall, and a suction lumen, to form a bleb of tissue into the suction cavity when suction is applied. The suction cavity extends along one side of the suction pad, so that the suction pad and suction cavity can be applied tangentially against a tissue site. The suction tool can incorporate light emission (52) and video imaging of tissue adjacent the suction pad. A working lumen (20) terminating in a working lumen port (46) into the suction cavity enables introduction of tools, cardiac leads, and other instruments, cells, drugs or materials into or through the tissue bleb drawn into the suction cavity.

WO 2004/064647 A1



SL, SZ, TZ, UG, ZM, ZW); Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

**Published:**

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

## METHODS AND APPARATUS FOR ACCESSING AND STABILIZING AN AREA OF THE HEART

### CROSS-REFERENCE TO RELATED APPLICATIONS

Reference is hereby made to commonly assigned U.S. Patent Application Serial No. 10/283,794 filed October 30, 2002, for METHODS AND APPARATUS FOR ACCESSING AND STABILIZING AN AREA OF THE HEART in the names of Gary W. Guenst et al., U.S. Patent Application Serial No. / filed January 15, 2003, for METHODS AND TOOLS FOR ACCESSING AN ANATOMIC SPACE in the name of Gary W. Guenst, and U.S. Patent Application Serial No. 10/284,771 filed October 31, 2002, for ANATOMIC SPACE ACCESS SUCTION TOOLS AND METHODS in the names of Koen Michels et al.

### FIELD OF THE INVENTION

The present invention pertains to medical devices and methods for accessing an anatomic surface, muscle layer, vessel or anatomic space of the body and particularly for entering the pericardium to access pericardial space and the epicardial surface of the heart, particularly to implant a cardiac lead in a minimally invasive manner.

### BACKGROUND OF THE INVENTION

The human heart wall consists of an inner layer of simple squamous epithelium, referred to as the endocardium, overlying a variably thick heart muscle or myocardium and is enveloped within a multi-layer tissue structure referred to as the pericardium. The innermost layer of the pericardium, referred to as the visceral pericardium or epicardium, clothes the myocardium. The epicardium reflects outward at the origin of the aortic arch to form an outer tissue layer, referred to as the parietal pericardium, which is spaced from and forms an enclosed sac extending around the visceral pericardium of the ventricles and atria. An outermost layer of the pericardium, referred to as the fibrous pericardium, attaches the parietal pericardium to the sternum, the great vessels and the diaphragm so that the heart is confined within the middle mediastinum. Normally, the visceral pericardium and parietal pericardium lie in close contact with each other and are separated only by a thin layer of a serous pericardial fluid that enables friction free movement of the heart within the sac. The

space (really more of a potential space) between the visceral and parietal pericardia is referred to as the pericardial space. In common parlance, the visceral pericardium is usually referred to as the epicardium, and epicardium will be used hereafter. Similarly, the parietal pericardium is usually referred to as the pericardium, and pericardium will be used hereafter in reference to parietal pericardium.

*It is frequently medically necessary to access the pericardial space to treat an injury, infection, disease or defect of the heart, e.g., an occluded coronary artery, a defective heart valve, aberrant electrical pathways causing tachyarrhythmias, bacterial infections, to provide cardiac resynchronization therapy, or to place epicardial pacing or cardioversion/defibrillation electrodes against the epicardium or into the myocardium at selected sites. It is necessary in these procedures to surgically expose and cut through the pericardium to obtain access to the pericardial space.*

Highly invasive surgical techniques, referred to as a median sternotomy (open-chest surgical exposure) or a thoracotomy, have been typically employed to provide the surgeon access to the pericardial space and the heart. A median sternotomy incision begins just below the sternal notch and extends slightly below the xyphoid process. A sternal retractor is used to separate the sternal edges for optimal exposure of the heart. Hemostasis of the sternal edges is typically obtained using electrocautery with a ball-tip electrode and a thin layer of bone wax.

The open chest procedure involves making a 20 to 25 cm incision in the chest of the patient, severing the sternum and cutting and peeling back various layers of tissue in order to give access to the heart and arterial sources. As a result, these operations typically require large numbers of sutures or staples to close the incision and 5 to 10 wire hooks to keep the severed sternum together. Such surgery often carries additional complications such as instability of the sternum, post-operative bleeding, and mediastinal infection. The thoracic muscle and ribs are also severely traumatized, and the healing process results in an unattractive scar. Post-operatively, most patients endure significant pain and must forego work or strenuous activity for a long recovery period.

Many minimally invasive surgical techniques and devices have been introduced in order to reduce the risk of morbidity, expense, trauma, patient mortality, infection, and other complications associated with open-chest cardiac surgery. Less traumatic limited open chest

techniques using an abdominal (sub-xyphoid) approach or, alternatively, a "Chamberlain" incision (an approximately 8 cm incision at the sternocostal junction), have been developed to lessen the operating area and the associated complications. In recent years, a growing number of surgeons have begun performing coronary artery bypass graft (CABG) procedures using minimally invasive direct coronary artery bypass grafting (MIDCAB) surgical techniques and devices. Using the MIDCAB method, the heart typically is accessed through a mini-thoracotomy (i.e., a 6 to 8 cm incision in the patient's chest) that avoids the sternal splitting incision of conventional cardiac surgery. A MIDCAB technique for performing a CABG procedure is described in U.S. Patent No. 5,875,782, for example.

Other minimally invasive, percutaneous, coronary surgical procedures have been advanced that employ multiple small trans-thoracic incisions to and through the pericardium, instruments advanced through ports inserted in the incisions, and a thoracoscope to view the accessed cardiac site while the procedure is performed as shown, for example, in U.S. Patent Nos. 6,332,468, 5,464,447, and 5,716,392. Surgical trocars having a diameter of about 3 mm to 15 mm are fitted into lumens of tubular trocar sleeves, cannulae or ports, and the assemblies are inserted into skin incisions. The trocar tip is advanced to puncture the abdomen or chest to reach the pericardium, and the trocar is then withdrawn leaving the sleeve or port in place. Surgical instruments and other devices such as fiber optic thorascopes can be inserted into the body cavity through the sleeve or port lumens. As stated in the '468 patent, instruments advanced through trocars can include electrosurgical tools, graspers, forceps, scalpels, electrocauteries, clip applicators, scissors, etc.

In such procedures, the surgeon can stop the heart by utilizing a series of internal catheters to stop blood flow through the aorta and to administer cardioplegia solution. The endoscopic approach utilizes groin cannulation to establish cardio-pulmonary bypass (CPB) and an intraaortic balloon catheter that functions as an internal aortic clamp by means of an expandable balloon at its distal end used to occlude blood flow in the ascending aorta. A full description of an example of one preferred endoscopic technique is found in U.S. Patent No. 5,452,733, for example.

However, recently developed, beating heart procedures disclosed in U.S. Patent No. 6,394,948, for example, eliminate the need for any form of CPB, the extensive surgical procedures necessary to connect the patient to a CPB machine, and to stop the heart. These

beating heart procedures can be performed on a heart exposed in a full or limited thoracotomy or accessed percutaneously.

In such percutaneous procedures, the epicardium of the beating or stopped heart is exposed to view typically by use of grasping and cutting instruments inserted through one port to cut through the pericardium surrounding the heart while the area is viewed through the thoracoscope or endoscope inserted through another port. The thoracoscopic approach typically requires the placement of a chest tube and admission to the hospital for the initial 1-2 post-operative days.

Therefore, much effort has been expended to develop medical devices and techniques to access the pericardial space employing such minimally invasive percutaneous procedures. One difficulty has been that normally the pericardial space is so small or thin that it is difficult to penetrate the pericardium using miniaturized instruments capable of being introduced through a port to the site without also puncturing the underlying epicardium and thereby, damaging the myocardium or a coronary vessel. Proliferative adhesions occur between the pericardium and the epicardium in diseased hearts and hamper access to the pericardial space employing such minimally invasive percutaneous procedures. The simple percutaneous approach can be used to penetrate the pericardium to drain a large pericardial effusion, i.e., an accumulation of too much fluid in the pericardial space that widens the pericardial space. A spinal needle (18-20 gauge) and stylet occluding the needle lumen are advanced incrementally in a superior/posterior fashion through a small (2-4 mm) cutaneous incision between the xyphoid and costal cartilage. Periodically, the stylet is removed, and fluid aspiration is attempted through the needle lumen. The advancement is halted when fluid is successfully aspirated, and the pericardial effusion is then relieved.

Methods and apparatus for accessing the pericardial space for the insertion of implantable defibrillation leads are disclosed in U.S. Patent Nos. 5,071,428 and 6,156,009, wherein a forceps device is used to grip the pericardium and pull it outward to form a "tent". In the '428 patent, a scissors or scalpel is introduced to cut the pericardium (pericardiotomy) under direct vision through a sub-xyphoid surgical incision. The forceps device disclosed in the '009 patent incorporates a mechanism for introducing electrical leads or guidewires through the outwardly displaced pericardium. It is difficult to introduce and use the forceps

through the narrow lumen of a port or sleeve, particularly if the pericardial fluid is under pressure that makes the pericardium taut like an inflated balloon.

Further methods and apparatus for accessing the pericardial space for the insertion of devices or drugs are disclosed in U.S. Patent No. 6,423,051, wherein an access tube having a device access lumen is provided with a plurality of hooks in the tube distal end that can be used to hook into the pericardium to enable the lifting and "tenting" of the pericardium. A cutting instrument or sharpened tip guidewire or the like can be advanced through the device access lumen to perforate the pericardium.

Other methods and apparatus that are introduced through percutaneously placed ports or directly through small trans-thoracic incisions for accessing the pericardial space employ suction devices to grip the pericardium or epicardium as disclosed, for example, in U.S. Patent Nos. 4,991,578, 5,336,252, 5,827,216, 5,868,770, 5,972,013, 6,080,175, and 6,231,518 and the above-referenced '948 patent. The suction devices are configured like a catheter or tube having a single suction tool lumen and typically having a further instrument delivery lumen. The suction tool lumen terminates in a single suction tool lumen end opening through the device distal end in the '578, '252, '175, '770, and '013 patents and through the device sidewall in the '216 and '518 patents. Certain of these patents recite that the applied suction draws a "bleb," i.e., a locally expanded region of the pericardium, into the suction tool lumen or a suction chamber at the device distal end. A needle can then be advanced into the bleb and used to draw off fluids or deliver drugs into the pericardial space, or the like. In addition, it is suggested in these patents that treatment devices including catheters, guidewires, and electrodes, e.g., defibrillation electrodes, can be advanced into the pericardial space through a device introduction lumen for a variety of reasons. Although theoretically plausible, the ability to reliably maintain a vacuum seal against the pericardium when such treatment devices are advanced can be problematic.

For these reasons, it would be desirable to provide additional and improved methods and apparatus for the minimally invasive access to a patient's pericardial space. The methods and devices should be suitable for a wide variety of minimally invasive approaches to the pericardium, including at least intercostal/trans-thoracic and subxiphoid approaches, and the like. The methods and devices should further provide for secure and stable capture of the pericardium and permit the opening of a large space or volume between the pericardium and

epicardium. Such access methods and apparatus should be useful for a wide variety of procedures to be performed in the pericardial space, including fluid withdrawal, drug delivery, cell delivery, diagnostic and therapeutic electrophysiology procedures, pacemaker lead implantation, defibrillator lead placement, transmyocardial revascularization, transmyocardial revascularization with drug delivery, placement of the left ventricular assist devices, placement of the arterial bypass graphs, in situ bypass, i.e., coronary artery-venous fistulae, placement of drug delivery depots, closure of the left arterial appendage, and the like. At least some of these objectives will be met by the invention described herein.

#### SUMMARY OF THE INVENTION

In accordance with a preferred embodiment of the present invention, an elongated suction tool is introducible through a percutaneous pathway, e.g., through the lumen of a percutaneous sleeve extending from the skin to a lateral surface of a tissue site. The suction tool incorporates a suction pad concave wall defining a suction cavity, a plurality of suction ports arrayed about the concave wall, and a suction lumen, to form a bleb of tissue into the suction cavity when suction is applied. The suction cavity extends along one side of the suction pad, so that the suction pad and suction cavity can be applied tangentially against a tissue site.

Preferably, the suction tool incorporates one or more light emitter to illuminate the tissue, a camera or a light pipe to an external video camera and display to image the illuminated tissue, and a working lumen terminating in a working lumen port into the suction cavity to introduce tools, cardiac leads, and other instruments, drugs or materials into or through the tissue bleb drawn into the suction cavity.

In accordance with a further aspect of the invention, the suction pad distal end is shaped to form a tissue dilator to be inserted through an incision made through the tissue to facilitate advancement of the suction pad through the incision.

In accordance with a still further aspect of the invention, the distal suction pad and a distal segment of the suction tool body are deflectable to steer the suction pad to a desired illuminated and imaged tissue site, e.g., a site of the pericardium or the epicardium.

The methods, suction tool and tool kits of the present invention can advantageously be used to access the pericardial space between the pericardium and epicardium. Various tools and



devices can be introduced into the pericardial space for temporary treatment of the pericardial space or myocardium or to complete a cardiac surgical procedure or for permanent implantation against the epicardium or within the pericardial space or within the myocardium or within a coronary vein or artery.

One aspect of the present invention provides methods, apparatus, and kits for accessing a patient's pericardial space between the pericardium and the epicardium in a minimally invasive manner to enable implantation of a cardiac lead electrode through the pericardium and upon the epicardium or into the myocardium. The present invention will be also be useful for accessing the pericardial space for performing a wide variety of procedures, generally as set forth above, separately or ancillary to the implantation of the cardiac lead electrode.

In an exemplary cardiac lead implantation, the suction pad is laterally extended out of the percutaneous sleeve lumen distal end opening and applied tangentially against the pericardial surface. The light source and camera/video display are employed to visualize the positioning of the suction pad against the pericardium. Suction is applied through the suction lumen and suction ports to form a bleb of the pericardium into the suction cavity of the suction pad. A cutting instrument is introduced through the working lumen into the suction cavity to make an incision through the pericardial bleb. Other cutting or shaping instruments can be introduced through the working lumen port to lengthen the pericardial incision.

The cutting instrument can be a knife blade, a needle, a stiff guidewire tip, an electrosurgical cutting tool, surgical scissors, or other piercing or cutting tools. Preferably, the cutting instrument comprises a shaped cutting blade having a blade tip and a blade edge that facilitates perforating and cutting a slit through the pericardium to form an elongated pericardial incision.

At this point, the pericardial space is accessed, and the suction pad of the suction tool can be advanced into the pericardial space. The pericardial space can be illuminated and visualized employing the light source and camera/video display. Various tools, instruments, drugs, other materials and devices can be introduced through the working lumen into the illuminated and imaged pericardial space. For example, a distal portion of a cardiac lead can be introduced into the pericardial space to dispose one or more electrode, e.g., a large surface

area cardioversion/defibrillation electrode or indifferent pace/sense electrode, into the pericardial space to lodge against the epicardium.

The suction tool can be advanced through the pericardial incision to dispose the suction pad into lateral engagement with the epicardium. Again, the light source and camera/video display are employed to visualize the positioning of the suction pad against the epicardium. Suction is again applied to grip the epicardium and form a bleb of the myocardium within the suction cavity of the suction pad.

Thus, in accordance with yet another aspect of the invention, the suction tool can be employed to both form a pericardial bleb and a myocardial or myocardial bleb in succeeding steps of a method of accessing the pericardial space and affixing a cardiac lead electrode against the epicardium or in the myocardium.

One preferred use of the suction tool is to enable implantation of an epicardial cardiac lead having a fixation mechanism that is lodged into or through the myocardium into a heart chamber or tangentially through the myocardial bleb and against the epicardium. The fixation mechanism of such a cardiac lead is advanced through the working lumen and inserted into or through the myocardium to fix a pace/sense electrode in intimate contact with the myocardium or against the epicardium. The fixation mechanism can comprise, for example, a barbed hook that is pushed into the myocardium or a helix that is screwed into the myocardium. The hook or helix can be formed of an electrically conductive material to function as a pace/sense electrode in a manner well known in the art.

In a further variation of the suction tool, a suction cavity distal slot or recess can be provided in the distal end wall of the suction cavity that is generally aligned with the working lumen port. The distal recess can receive and act as a stop for the blade tip of the cutting blade and can also be employed to facilitate deployment of particular cardiac lead fixation mechanisms.

In the latter case, the distal recess receives the distal end of a cardiac lead and cardiac lead installation tool that is pushed through the myocardial bleb to dispose the cardiac lead distal end distal to a distal epicardial perforation. The distal end of a cardiac lead having a deployable distal fixation mechanism restrained by the installation tool can thereby be advanced through the myocardial bleb. The lead installation tool is manipulated to deploy the distal fixation mechanism within the suction cavity and against the epicardium, and the

installation tool is then retracted over the lead body through the working lumen. Suction is released, and the suction tool is then retracted over the cardiac lead.

The suction tool body and/or the working lumen can be circular or oval or have any other desirable cross-section shape. The suction tools of the present invention can have a non-circular cross-section to fit a non-circular cross-section working lumen so as to optimize the shape of the suction pad and suction cavity and to ensure that the cutting instrument does not rotate within the working lumen as it is advanced therethrough and used to make the tissue incision.

The tubular suction tool body can be straight, curved or formed with a bend or formed of a bendable material to be shaped by the user. The suction cavity of the suction pad can be relatively elongated in axial alignment with the suction tool body, e.g., in the shape of a closed or open-ended half-pipe, or can be hemispheric in shape.

Advantageously, there is no suction applied through the working lumen that is necessary to maintain the attachment to the pericardium or epicardium while it is being perforated or while other devices or materials of the types described above are advanced through working lumen to make or pass through the incision or perforation. Moreover, it is simpler to advance such cutting instruments, cardiac leads, other devices and materials through the working lumen from a proximal lumen end opening that is exposed to the atmosphere.

This summary of the invention has been presented here simply to point out some of the ways that the invention overcomes difficulties presented in the prior art and to distinguish the invention from the prior art and is not intended to operate in any manner as a limitation on the interpretation of claims that are presented initially in the patent application and that are ultimately granted.

#### BRIEF DESCRIPTION OF THE DRAWINGS

These and other advantages and features of the present invention will be more readily understood from the following detailed description of the preferred embodiments thereof, when considered in conjunction with the drawings, in which like reference numerals indicate identical structures throughout the several views, and wherein:

FIG. 1 is an illustration of the preparation of a patient for accessing the pericardial space through the use of a suction tool of the present invention introduced through the sleeve lumen of a percutaneously placed tubular access sleeve in preparation for advancement of a cutting instrument through the working lumen of the suction tool for making an incision through the epicardium;

FIG. 2 is cross-section view of the patient's thorax depicting the advancement of the suction pad at the suction tool distal end against the pericardium;

FIG. 3 is an illustration of the advancement of the suction tool within the sleeve lumen when the distal suction pad of the suction tool is advanced through an incision in the pericardium in preparation for advancement of a cardiac lead through the working lumen of the suction tool to enable screwing of a fixation helix of the cardiac lead into the myocardium;

FIG. 4 is a plan view of the distal suction pad of the suction tool of FIGs. 1-3;

FIG. 5 is a perspective view of the distal suction pad of the suction tool of FIGs. 1-3;

FIG. 6 is a schematic illustration of the application of suction through the suction ports of the suction pad to form a pericardial bleb;

FIG. 7 is a schematic illustration of the advancement of a cutting instrument through the working lumen of the suction tool and through the pericardium while suction continues to be applied through the suction ports of the suction pad to maintain the pericardial bleb;

FIG. 8 is a schematic illustration of the advancement of the suction tool through the incision made through the pericardium;

FIG. 9 is a schematic illustration of the application of suction through the suction ports of the suction pad against the epicardium to form a myocardial bleb;

FIG. 10 is a schematic illustration of the advancement of a cardiac lead through the working lumen of the suction tool and rotation of the lead body to screw the fixation helix of the cardiac lead into the myocardium;

FIG. 11 is a schematic illustration of a modification of the suction tool providing for the capability of deflecting the suction pad to steer it to a particular pericardial or epicardial site and to orient the suction cavity to the pericardium or epicardium to form a respective pericardial or myocardial bleb;

FIGs. 12A and 12B are schematic illustrations of a first alternate shape of the suction tool distal end to facilitate advancement through and widening of the incision in the pericardium as depicted in FIG. 8;

FIGs. 13A and 13B are schematic illustrations of a second alternate shape of the suction tool distal end to facilitate advancement through and widening of the incision in the pericardium as depicted in FIG. 8;

FIGs. 14A and 14B are schematic illustrations of a first alternate shape of the suction tool distal end to facilitate advancement through and widening of the incision in the pericardium as depicted in FIG. 8;

FIG. 15 is a schematic illustration of one shape of a cutting instrument blade of the cutting instrument advanced through the working lumen to form the incision through the pericardium as depicted in FIG. 7;

FIG. 16 is a schematic illustration of a further shape of a cutting instrument blade of the cutting instrument advanced through the working lumen to form the incision through the pericardium as depicted in FIG. 7;

FIG. 17 is a schematic illustration of a still further shape of a cutting instrument blade of the cutting instrument advanced through the working lumen to form the incision through the pericardium as depicted in FIG. 7;

FIG. 18 is a plan view of a further variation of the distal suction pad of the suction tool of FIGs. 1-11;

FIG. 19 is a perspective view of the distal suction pad of FIG. 18;

FIG. 20 is a schematic illustration of the application of suction through the suction ports of the suction pad of FIGs. 18 - 19 against the epicardium to form a myocardial bleb, and the advancement of a cardiac lead within a lead installation tool through the working lumen of the suction tool and the myocardial bleb;

FIG. 21 is a schematic illustration of the cardiac lead of FIG 20 lodged within the myocardial bleb upon retraction of the lead installation tool;

FIG. 22 is a schematic illustration of the cardiac lead of FIG 20 lodged within the myocardial bleb a distal fixation mechanism of the cardiac lead deployed against the epicardium distal to a distal epicardial perforation upon retraction of the lead installation tool; and

FIG. 23 is a schematic illustration of the cardiac lead of FIGs. 20 - 22 attached to the myocardium following removal of the suction tool.

The drawing figures are not necessarily to scale.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the following detailed description, references are made to illustrative embodiments of methods and apparatus for carrying out the invention. It is understood that other embodiments can be utilized without departing from the scope of the invention. Preferred methods and apparatus are described for accessing the pericardial space between the epicardium and the pericardium as an example of accessing an anatomic space between an outer tissue layer and an inner tissue layer.

For example, FIGs. 1 - 3 illustrate the placement of instruments through the chest wall of a patient 100 for observation and accessing the pericardial space through an incision in the pericardium 106 exposing the pericardium of the heart 104 to perform any of the ancillary procedures listed above. The patient 100 is placed under general anesthesia, and the patient's left lung is deflated if necessary, using conventional techniques. The patient 100 is placed in a lateral decubitus position on his right side, and small percutaneous incisions are to be made in the skin 102 through the chest wall for the receipt of surgical instruments. As used herein, the term "percutaneous" refers to any penetration through the skin of the patient, whether in the form of a small cut, incision, hole, cannula, tubular access sleeve or port or the like, that is preferably made in an interstitial space between the ribs of the patient 100.

First and second passages 108 and 118 are preferably made through the skin 102 into the thoracic cavity. The passages 108 and 112 are typically formed employing one-piece rods or trocars of prescribed diameters and lengths that are advanced through body tissue to form the passage and then removed so that other instruments can be advanced through the passage. The passage can also be formed employing two piece trocars that comprise a tubular outer sleeve, sometimes referred to as a port or cannula or at times as the tubular access sleeve itself, having a sleeve access lumen extending between lumen end openings at the sleeve proximal end and sleeve distal end, and an inner puncture core or rod that fits within the sleeve access lumen. The inner puncture rod typically has a tissue penetrating distal end that extends distally from the sleeve distal end when the inner puncture rod is fitted into the

sleeve access lumen for use. The two-piece trocar can be assembled and advanced as a unit through body tissue, and the inner puncture rod then removed leaving the tubular access sleeve in place to maintain a fixed diameter passage through the tissue for use by other instruments.

In one of these ways, a tubular access sleeve 110 is placed through first passage 108 that is made as described above in the chest wall of patient 100 between the patient's 2nd rib and 6th rib, for example. The selection of the exact location of the first passage 108 is dependent upon a patient's particular anatomy. A further conventional tubular access sleeve 112 is shown left in place in a second passage 110 that is made as described above in the chest wall of patient 100.

Typically, the patient's left lung is deflated to allow unobstructed observation of the pericardium 106 employing a thoracoscope 120 inserted through a sleeve lumen of tubular access sleeve 112. Frequently, the deflation is accomplished by use of a double lumen endotracheal tube that is inserted into the trachea, and independent ventilation of the right, left or both lungs can be selected. The left lung will collapse for visualization of the structures of the left hemi-sternum when ventilation of the left lung is halted and the left thoracic negative pressure is relieved through a lumen of the tubular access sleeve 112 or a further access sleeve to atmospheric pressure. After deflation, the thoracic cavity may be suffused with a gas, e.g., carbon dioxide, introduced through a lumen of the tubular access sleeve 112 or the further access sleeve to pressurize the cavity to keep it open and sterile. The pressurized gas keeps the deflated lung away from the left heart so that the left heart can be viewed and accessed and provides a working space for the manipulation of the tools of the present invention. It will be understood that the access sleeve lumens must be sealed with seals about instruments introduced through the lumens to maintain the pressurization. .

A thoracoscope 120 can then inserted into the lumen of the tubular access sleeve 112 to permit wide angle observation of the thoracic cavity by a surgeon directly through an eyepiece 122 or indirectly through incorporation of a miniaturized image capture device, e.g., a digital camera, at the distal end of the thoracoscope 120 or optically coupled to the eyepiece 122 that is in turn coupled to an external video monitor (not shown). The thoracoscope 120 also incorporates a light source for illuminating the cavity with visible light so that the epicardial surface can be seen directly or indirectly. The depicted thoracoscope 120 is used

to directly visualize the thoracic cavity and obtain a left lateral view of the pericardial sac or pericardium 106 over the heart 104.

The elongated access sleeve 110 provides an access sleeve lumen 116 enabling introduction of suction tool 10 to dispose the suction pad 30 within the thoracic cavity. The tubular access sleeve 110 and suction tool 10 of the present invention are employed to access the pericardium 106 and to grip its surface to tension it so that an incision can be made through the pericardium 106. The accessed pericardial space 124 and epicardium 106 surrounding the heart 104 are shown more specifically in the cross-section view of FIG. 2. A cutting instrument 80, e.g., a knife, a needle, a stiff guidewire tip, an electrosurgical cutting tool, surgical scissors, or other piercing or cutting instrument 80 is depicted in FIG. 1 poised to be inserted through the suction tool working lumen 14 to perforate a bleb of pericardium 106 within the suction cavity of the suction pad 30 and then form a pericardial incision 114 through the pericardial bleb exposing the pericardial space and exterior surface of the epicardium of the heart 104. Exemplary cutting blades that can be employed in cutting instrument 80 are disclosed herein.

The suction pad 30 is advanced through the incision formed through the pericardium and against the epicardium. In one preferred use of the suction tool of the present invention, a myocardial bleb is formed by the applied suction so that an epicardial lead can be attached to the myocardium by a fixation mechanism. An exemplary cardiac lead 90 having a distal fixation helix 92 that may also function as a pace/sense electrode is depicted in FIG. 3 poised to be advanced through the working lumen 20. The cardiac lead can take any of the forms known in the pacing art having one or more distal pace/sense electrodes coupled through one or more respective conductors within lead body 96 extending to one or more respective connector elements of a proximal connector assembly 94. Preferably the outer diameters of the distal fixation mechanism 92, the proximal connector assembly 94 and the lead body 96 are approximately the same or smaller and fit through the working lumen 20. The distal fixation mechanism 92 can comprise a fixation helix, prong or hook or can take other forms, and further examples are described below.

The suction tool 10 comprises a suction tool body 12 extending between a proximal suction tool port assembly 14 and a suction pad 30 depicted in greater detail in FIGs. 4 and 5. The suction tool body 12 and the distal suction pad 30 are sized to be inserted through an



incision or the access sleeve lumen 116 so that the suction pad 30 can first be introduced into the thoracic cavity and applied against the epicardium, then advanced through an incision made in the epicardium, and then applied against the myocardium.

The suction tool proximal assembly 14 comprises the proximal end opening of the suction tool working lumen 20, an optical or electrical illumination connector 22, a vacuum side port 24, and an optical or electrical imaging connector 26.

The vacuum side port 24 is adapted to be attached to a vacuum source at the surgical site to draw suction through one or more vacuum lumen extending through the suction tool proximal end assembly 14, the suction tool body 12 and then through a plurality of suction ports 42 of suction port array 40 depicted in FIGs. 4 and 5.

In accordance with one aspect of the present invention, the tissue sites, i.e., the pericardium, pericardial space and myocardium in this instance, adjacent to the suction pad are optionally illuminated and imaged through the suction tool 10. The illumination of the sites can be accomplished by one or more miniaturized light emitters incorporated into the suction pad 30 coupled to conductors extending through the tool body 12 to an electrical illumination connector 22 that is coupled to an external battery pack or the like. However, for safety, economic, and space reasons, it is preferred that light be conducted from an external light source to the suction pad 30. So, it will be understood that the suction tool 10 incorporates an optical illumination connector 22 including one or more fiber-optic light pipes extending to one or more light emitting lens elements and/or light pipe ends, e.g., light pipe ends 52 and 54 depicted in FIGs. 4 and 5. The light pipe ends 52 and 54 can be polished or surface treated to enhance dispersion of light and light brightness.

The illuminated tissue site could be imaged by incorporating a miniaturized video camera digital imaging array and lens in the suction pad 30 and powering the array and conducting image pixel data through conductors extending to an electrical imaging connector 26 to be coupled to external video imaging and display apparatus. However, for safety, economic, and space reasons, it is preferred that an image of the illuminated site be optically conveyed from an external light source to the suction pad 30. Again, it will be understood that the suction tool 10 incorporates an optical imaging connector 26 coupled with a fiber-optic light pipe extending to an imaging lens element or pipe end 38 depicted in FIGs. 4 and 5. The light pipe end 38 can be polished or shaped to function as a lens.

One preferred configuration of the non-conductive suction pad 30 is depicted in FIGs. 4 and 5. The suction pad 30 features a flat lower wall 32, a convex upper wall 34, a concave suction pad wall 36 extending into the flat wall 32 toward the convex upper wall 34 and a proximal cavity wall 38, whereby a suction cavity 50 is created that a bleb of tissue can be drawn into. A suction port array 40 comprises a plurality of suction ports 42 through the concave suction pad wall 36 from an interior manifold coupled with a suction lumen 44 extending the length of the tool body 12 to the suction side port 24. The orientation of the suction cavity 50 to the axis of the tool body 12 allows the suction cavity to be advanced tangentially to the surface of the tissue that is approached to be drawn into the suction cavity 50 as a tissue bleb.

The working lumen 20 extends through the tool body 12 and a proximal portion of the suction pad 30 to a working lumen port 46 in the proximal cavity wall 38 defining the suction cavity 50. Therefore, the various instruments such as cutting instrument 80 and cardiac lead 90 referred to herein can be advanced tangentially into the tissue bleb.

It should be noted that the working lumen 20 can also be the suction lumen 44 in suction tools specifically designed to introduce medical instruments and devices, rather than fluids or materials, through the combined lumen. Suction would then be applied to the tissue bleb through the working lumen port 46 as well as the array of suction ports

Optionally, an illumination light pipe 48 extends from the optical illumination connector 22 through the length of the tool body 12 and branches within the proximal portion of the suction pad 30 to a pair of illumination light pipe ends 52 and 54 in proximal suction pad wall 38. Similarly, optionally, an imaging light pipe 56 extends from the optical imaging connector 26 through the length of the tool body 12 and the proximal portion of the suction pad 30 to an imaging light pipe end 58 in proximal cavity wall 38. Therefore, the area within the concave suction wall 36 and distal to the suction pad distal end 62 can be illuminated and imaged remotely. It should be noted that the light pipes 48 and 56 can be extended past the suction cavity 50 to terminate with the light pipe ends 52, 54 and 56 arrayed near the suction pad distal end 60. Or, the light pipes can extend simply to the more proximal suction pad wall 62 and terminate with the light pipe ends 52, 54 and 56 arrayed in the more proximal suction pad wall 62.

In use, the suction pad 30 is laterally extended out of the suction tool lumen 20 so that a tangential approach can be made to the tissue, such as the pericardium 106 as shown in FIG. 2. The area is optionally illuminated and imaged as described above, and suction is applied to draw a pericardial bleb 136 into the suction cavity 50 as shown in FIG. 6. The pericardial space 138 can then be tented away from the heart 104.

In FIG. 7, the cutting instrument 80 is advanced through the working lumen 20 and the blade 84 is advanced out of the working lumen port 46 through a pericardial perforation and along the pericardium 106 to form the pericardial incision 114. The length of the pericardial incision 114 generally corresponds to the length of the suction cavity 50. The pericardial incision therefore has a perimeter that is larger than the perimeter of the cross section of the suction pad 30, enabling the suction pad to be advanced through the pericardial incision 114.

Advantageously, there is no suction applied through the suction tool working lumen 20 that is necessary to maintain the attachment of the pericardium 106 while it is being cut to form the pericardial incision 114 to reach the pericardial space 138. Due to their redundancy, the plurality of suction ports 42 of the suction pads 30 provide more robust fixation to the pericardium 106 (or other outer tissue layer) than a single large area suction port. At least some of the suction ports 42 readily engage the pericardial surface under low suction force to maintain the pericardial bleb 136 and enable lifting of the pericardium 106 or tracking movement of the pericardium 106. Engagement of the surface of the pericardium 106 by all of the suction ports 42 is not necessary. Similarly, the loss of engagement of some of suction ports 42 with the surface areas of the pericardium 106 does not result in complete loss of engagement as is the case when an edge of a single large suction port releases from a tissue surface of an outer tissue layer or the pericardium.

Furthermore, the suction tool 10 is versatile in that it can be used to simply access the pericardial space 138. Various instruments, medical devices, drugs or materials can be advanced through the working lumen 20, out of the working lumen port 46, through the pericardial incision 114, and into the pericardial space 138 for temporary treatment of the heart 104 or pericardial space 138 or to complete a surgical procedure or for permanent implantation of medical devices against the epicardium 140 or within the pericardial space or within the myocardium 142 or within a coronary vein or artery.

However, a preferred use of the suction tool 10 to enable implantation of the cardiac lead 90 is further illustrated in FIGs. 8 - 10. The cutting instrument 80 is withdrawn from the working lumen 20, and the pericardial bleb 136 is released from the suction cavity 50. The suction tool 10 is manipulated to insert the suction pad distal end 60 into the illuminated and imaged pericardial incision 114 as shown in FIG. 8. The suction pad 30 is inserted through the pericardial incision 114 and advanced into the pericardial space 138 with the suction cavity 50 facing the epicardium 140. Suction is then restored through the suction ports 42, and a myocardial bleb 146 is drawn into the suction cavity 50 as shown in FIG. 9.

The cardiac lead 90 is then advanced through the working lumen 20 to dispose the active fixation helix 92 at the working lumen port into the suction cavity 50. The cardiac lead body is then rotated at the proximal connector assembly in the proper direction to screw the fixation helix 92 through the epicardium 140 and into the myocardial bleb 146. Sensing and pacing threshold measurements are made in the conventional manner. The suction tool 10 is withdrawn over the lead body if acceptable thresholds are realized. The fixation helix 92 can be released if the thresholds are not acceptable, and the process of FIGs. 7-10 repeated until an acceptable site is found. The lead body is routed to the implantation site of an implantable pulse generator (IPG), and the lead connector assembly is coupled to the IPG in the conventional manner.

In accordance with a still further aspect of the invention, the suction tool 10 is equipped with a steering mechanism that the surgeon can manipulate at the suction tool proximal end assembly 14 to steer the suction pad 30 to a desired illuminated and imaged tissue site, e.g., a site of the pericardium or the epicardium illustrated in FIGs. 6-10. Such a capability is schematically depicted in FIG. 11. A deflection mechanism 70 can be incorporated into the suction tool body 12 that the user can manipulate to induce a bend in a distal segment 72 of suction tool body 12 to deflect the suction pad 30 from position "A" to position "B", for example, generally defining a range of motion in a single plane. The deflection mechanism 70 can be manipulated to steer the suction pad 30 to a particular pericardial or epicardial site and to orient the suction cavity 50 to the pericardium or epicardium to form a respective pericardial or myocardial bleb.

The deflection mechanism can take any of the forms known in the medical device art. A commonly employed approach to providing controllable deflection of the distal end

segments of catheters, guidewires, and stylets employs a generally straight outer sheath or tube and a pull or push or push-pull wire extending through a lumen of the outer sheath to an attachment point at the sheath distal end. The wire is pushed or pulled on at its proximal end typically through a handle that is permanently or removably attached to the catheter or guidewire proximal end. The proximal retraction or distal advancement of the pull or push wire, respectively, causes at least a distal segment of the outer sheath to bend or deflect. Examples of such deflection mechanisms in catheters can be found in U.S. Patent Nos. 4,815,478, 4,898,577, 4,940,062, 5,545,200 and 6,251,092. U.S. Patent Nos. 4,815,478 and 4,940,062 disclose the use of push-pull wires extending through guidewire lumens for deflecting a guidewire distal end by manipulating a handle at the guidewire proximal end.

Thus, deflection mechanism 70 can comprise a proximal handle at the suction tool proximal end assembly 14 coupled to a pair of pull wires extending from handle controls to opposite sides of the suction pad 30 to selectively induce bends in distal segment 72 to move the suction pad between positions "A" and "B" and intermediate positions therebetween.

In accordance with a further aspect of the invention, the suction pad distal end 60 is shaped to facilitate advancement of the suction pad through the tissue incision to facilitate advancement of the suction pad 30 through and widening of the pericardial incision 114 as depicted in FIG. 8. For example, shaped suction pad distal ends 60', 60'', and 60''' of respective suction pads 30', 30'', 30''' are depicted in FIGs. 12A - 12B, 13A - 13B, and 14A - 14B, respectively. The depicted "shovel" or "snout" shapes of suction pad distal ends 60', 60'', and 60''' generally are shaped to provide a leading end or "leader" 74', 74'', 74''' that can be easily inserted into the tissue incision, particularly the pericardial incision 114, followed by a "dilator" 76', 76'', 76''' to widen the pericardial incision 114 as the respective suction pad 30', 30'', 30''' is inserted through it. The leader 74' is a rounded tip, the leader 74'' is a pointed tip, and the leader 74''' is ball-tip.

Returning to the cutting instrument, cutting blade 84 of FIGs. 1 and 7 can be shaped in a variety of ways, e.g., the exemplary blades 84', 84'' and 84''' depicted in FIGs. 15 - 17 to facilitate making the tissue incision, particularly the pericardial incision 114 through the pericardium 106. Generally, like cutting blade 84, the cutting blades 84' and 84'' incorporate a sharpened perforation tip 88' and 88'' and trailing cutting blade edges 85' and 85''. The cutting blade 84''' incorporates a blunt leading tip 88''' . Trailing cutting blade edges 85',

85'' and 85''' make the tissue incision, through the tissue layer held against the convex upper wall 36 by suction. In this way, the pericardial incision 114 can be made through the pericardial bleb 136 maintained by suction in the suction cavity 50 as depicted in FIG. 7. The cutting blade 84' of FIG. 15 comprises the sharpened perforation tip 88' and "V" shaped blade edge 85'. The pericardium 106 is punctured by the sharpened perforation tip 88' and is slitted as it is trapped in the "V" shaped blade edge 85' while the cutting blade 84' is advanced through the elongated suction cavity 50.

The cutting blade 84'' of FIG. 16 comprises a sharpened leading blade point 85'' and the elongated blade edge 85'' that is inverted from the blade edge orientation shown in cutting blade 84. The cutting blade 84'' is advanced through the tissue, e.g., the pericardium 106, to make a relatively limited tissue incision, e.g., a limited size pericardial incision 114. The cutting blade 84''' of FIG. 17 can be used after such a limited tissue incision is made by use of a cutting instrument having a cutting blade 84'' of FIG. 16. The cutting blade 84''' comprises the blunt leading blade point 85''' and the trailing "V" shaped blade edge 85'''. The blunt leading blade point 85''' is advanced through the pericardial incision 114, and the pericardium is slitted as it is trapped in the "V" shaped blade edge 85''' while the cutting blade 84''' is advanced through the elongated suction cavity 50.

The suction tool 10 as described above can be further modified to facilitate making and increasing the length of such tissue incisions, e.g. pericardial incision 114, and to facilitate implantation of cardiac leads into or through the myocardial bleb 146. In particular, an elongated, tapered, suction pad distal end 60'''' is depicted in the suction pad 30'''' of FIGs. 18 and 19 enclosing a distally extending slot or recess 47. The distally extending slot or recess 47 is axially aligned with the working lumen 20 and the working lumen port 46 as shown in FIGs. 18 and 19. Thus, the cutting instrument 80 can be pushed distally so as to advance the cutting blades 84, 84', 84'', 84''' all the way across the tissue bleb, e.g., pericardial bleb 136 of FIG. 7, to lodge the cutting blade distal tip 88, 88', 88'', and 88''' within the recess 47. Then, the cutting tool can be withdrawn, and the suction pad 30'''' can be advanced into the pericardial space, steered to a desired site of the epicardium under visualization, and deployed against the epicardium, as described above. Suction can be applied to draw the myocardial bleb 146 into the suction cavity 50.

Referring to FIGs. 20 - 23, the distal slot or recess 47 of the modified suction pad 30''' can also be used to facilitate deployment of particular cardiac leads having distal fixation mechanisms in the myocardial bleb 146 or distal to the myocardial bleb 146. After the myocardial bleb 146 is formed in suction cavity 50, the assembly of an exemplary cardiac lead 150 and cardiac lead installation tool 160 is inserted through the suction tool working lumen 20 and advanced through the myocardial bleb 146 as shown in FIG. 20. The cardiac lead distal fixation mechanism 154 (shown in FIG. 22) is restrained within or by the cardiac lead installation tool 160 during such advancement.

The installation tool 160 can comprise a catheter-like instrument having a installation tool lumen that the cardiac lead body and distal fixation mechanism is fitted into. The installation tool distal end 162 can comprise a conductive surface coupled through a conductor or a conductive tool shaft wall to the installation tool proximal end to be coupled with external test equipment to determine pacing and sensing thresholds.

The installation tool distal end 162 is preferably needle-shaped to pass through the myocardial bleb 146, in a path through a proximal perforation of the epicardium 140, the myocardium 142 and back through a distal perforation of the epicardium 140, and into the distal recess 47. In this way, the distal recess 47 receives the distal end 152 of the cardiac lead 150 and the distal end 162 of the cardiac lead installation tool 160 that is pushed through the myocardial bleb 146 to dispose the cardiac lead distal end 152 and the distal fixation mechanism 154 distal to the distal epicardial perforation. A cardiac electrode 158, e.g., a pace/sense electrode, is positioned to be disposed within the myocardial bleb 146 when the fixation tool is withdrawn over the cardiac lead 150 as depicted in FIG. 21.

The deployable distal fixation mechanism 154 at the cardiac lead distal end 152 restrained by the installation tool can thereby be advanced through the myocardial bleb 146 and into the distal recess 47. The lead installation tool 160 is manipulated, e.g., simply by retracting the installation tool distal end 162, to release the distal fixation mechanism 154 within the distal recess 47 and is then fully retracted over the cardiac lead 150, leaving the cardiac lead disposed as shown in FIG. 22.

The cardiac lead 150 can then be retracted sufficiently to release the distal fixation mechanism 154 from the distal recess 47 so that it bears against the epicardium 140 outside of the distal epicardial perforation as shown in FIG. 23. The distal fixation mechanism 154

preferably comprises one of a spiral that can be wound down to fit a lumen of the cardiac lead installation tool 160. One example of a screw-in lead is disclosed in U.S. Patent No. 5,076,285 to Hess et al., incorporated herein by reference. The distal fixation mechanism 154 may comprise one or more elongated flexible, metal or silicon rubber or polyurethane pliant hooks, prongs or tines that can be flattened or otherwise aligned with and restrained within a lumen of the cardiac lead installation tool 160. One example of a tined lead is disclosed in U.S. Patent No. 3,902,501 to Citron and Dickhudt, incorporated herein by reference. An exemplary three-tined fixation mechanism is depicted in FIGs. 22 and 23 that can be folded to fit into an installation tube lumen and that springs back into shape when released.

Suction is then interrupted allowing the suction tool 10 to be retracted over the cardiac lead 150. The myocardial bleb 146 flattens out, leaving the distal section of the lead body including the cardiac pace/sense electrode 158 within the myocardium 142 and extending out of the proximal and distal epicardial perforations 144 and 148. The flexible tined distal fixation mechanism 154 bears against the epicardium 140 to resist withdrawal of the cardiac pace/sense electrode 158 within the myocardium 142.

The suction tool 10 can be further modified to incorporate a pair of elongated electrodes attached to the suction pad lower wall extending alongside the suction cavity 50. In use, suction is applied to form the pericardial bleb 136, and ablation current can be applied to the electrodes that would create the pericardial incision 114. The electrodes can also be used when the suction pad 30 is applied to the epicardium 140 to conduct a mapping and threshold determination to locate optimal pace/sense sites for implantation of cardiac electrodes.

The tubular access sleeve 10 can be circular or oval or have any other desirable cross-section shape. The tubular access sleeve 10 can be straight, curved or formed with a bend or formed of a bendable material to be shaped by the user.

The access to the pericardial space in accordance with the present invention facilitates the performance of a number of ancillary procedures. For example, the procedures include introducing and locating the distal end of a catheter or guidewire or an electrode of a cardiac ablation catheter or a pacing lead or a cardioversion/defibrillation lead within the pericardial space and attached to the epicardium or myocardium. Other possible procedures include performing a coronary artery anastomosis in a thoracoscopic CABG procedure, replacing a



defective heart valve, ablating aberrant electrical pathways in the atria to alleviate atrial tachyarrhythmias, introducing cells, drugs or anti-bacterial agents into the pericardial space, relieving pericardial fluid pressure or providing cardiac resynchronization therapy. Other procedures that can be performed in the pericardial space, include fluid withdrawal, drug delivery, cell delivery, diagnostic and therapeutic electrophysiology procedures, transmyocardial revascularization, transmyocardial revascularization with drug delivery, placement of the left ventricular assist devices, placement of the arterial bypass graphs, in situ bypass, i.e., coronary artery-venous fistulae, placement of drug delivery depots, closure of the left arterial appendage, and the like.

All patents and publications referenced herein are hereby incorporated by reference in their entireties.

It will be understood that certain of the above-described structures, functions and operations of the above-described preferred embodiments are not necessary to practice the present invention and are included in the description simply for completeness of an exemplary embodiment or embodiments.

In addition, it will be understood that specifically described structures, functions and operations set forth in the above-referenced patents can be practiced in conjunction with the present invention, but they are not essential to its practice. It is therefore to be understood, that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described without actually departing from the spirit and scope of the present invention.

**CLAIMS:**

1. A suction tool for accessing the epicardium of the heart through an incision through the pericardium and into the pericardial space to implant an electrode of an epicardial cardiac lead within the myocardium or against the epicardium comprising:  
a suction tool body extending between a suction tool body proximal end and a suction tool body distal end; and  
an elongated suction pad extending between a suction pad proximal end and a suction pad distal end, the suction pad proximal end attached to the suction tool body distal end, the suction pad shaped to have a suction cavity adapted to be applied against tissue, the suction cavity defined by an elongated, substantially concave suction cavity wall bounded by a suction cavity rim, a plurality of suction ports extending through the suction cavity wall into the suction cavity, the suction pad distal end shaped with a leader to fit through a pericardial incision and a tissue dilator to be inserted through the pericardial incision to facilitate advancement of the suction pad into the pericardial space,  
the suction tool body further comprising:  
a suction lumen extending from a proximal suction fitting adapted to be coupled to a vacuum source and to the plurality of suction ports through which suction is applied to the pericardium to draw a pericardial bleb of the pericardium into the suction cavity when the suction cavity wall is applied against the pericardium and through which suction is applied to the epicardium to draw an myocardial bleb of the myocardium into the suction cavity when the suction pad is inserted through an incision of the pericardium into the suction cavity wall and applied against the epicardium; and  
a working lumen extending between a working lumen proximal end opening and an working lumen distal end opening into the suction cavity, the working lumen adapted to receive a cutting instrument having a cutting element for cutting into the pericardial bleb to form a pericardial incision through which the suction pad can be advanced into the pericardial space, the working lumen further adapted to receive a cardiac lead having a distal electrode and a lead fixation mechanism for maintaining the distal electrode in contact with the myocardium.

2. The suction tool of Claim 1, wherein the suction tool further comprises:  
a light conducting pipe extending between a light conducting pipe proximal end adapted to be coupled to a light source outside the patient's body and a light emitting distal end at the suction pad located to provide illumination about the suction pad; and  
an image conducting pipe extending between an image conducting pipe proximal end adapted to be coupled to an image capturing camera and image display outside the patient's body and an image conducting pipe at the suction pad to image the pericardium or epicardium adjacent the suction pad.

3. The suction tool of Claim 1, wherein the suction tool further comprises:  
a light conducting pipe extending between a light conducting pipe proximal end adapted to be coupled to a light source outside the patient's body and a light emitting distal end at the suction cavity wall located to provide illumination about the suction cavity wall; and  
an image conducting pipe extending between an image conducting pipe proximal end adapted to be coupled to an image capturing camera and image display outside the patient's body and an image conducting pipe at the suction cavity wall to image the pericardium or epicardium adjacent the suction cavity wall.

4. The suction tool of Claim 1, wherein the suction tool further comprises:  
a light conducting pipe extending between a light conducting pipe proximal end adapted to be coupled to a light source outside the patient's body and a light emitting distal end adjacent the tissue dilator to provide illumination about the suction pad distal end; and  
an image conducting pipe extending between an image conducting pipe proximal end adapted to be coupled to an image capturing camera and image display outside the patient's body and an image conducting pipe adjacent the tissue dilator to image the pericardium or epicardium adjacent the suction pad distal end.

5. The suction tool of Claim 1, wherein the suction tool further comprises:  
means for providing illumination of the pericardium or epicardium adjacent the suction pad;  
and  
means for providing an image of the illuminated pericardium or epicardium adjacent the suction pad.

6. The suction tool of Claim 1, wherein the suction tool further comprises:  
means for providing illumination of the pericardium or epicardium adjacent the suction cavity wall; and  
means for providing an image of the illuminated pericardium or epicardium adjacent the suction cavity wall.

7. The suction tool of Claim 1, wherein the suction tool further comprises:  
means for providing illumination of the pericardium or epicardium adjacent the tissue dilator to provide illumination about the suction pad distal end; and  
means for providing an image of the illuminated pericardium or epicardium adjacent the tissue dilator to image tissue adjacent the suction pad distal end.

8. A system for accessing the epicardium of the heart through an incision through the pericardium and into the pericardial space to implant an epicardial cardiac lead comprising:  
a suction tool comprising:  
a suction tool body extending between a suction tool body proximal end and a suction tool body distal end; and  
an elongated suction pad extending between a suction pad proximal end and a suction pad distal end, the suction pad proximal end attached to the suction tool body distal end, the suction pad shaped to have a suction cavity adapted to be applied against tissue, the suction cavity defined by an elongated, substantially concave suction cavity wall bounded by a suction cavity rim, a plurality of suction ports extending through the suction cavity wall into the suction cavity, the suction pad distal end shaped to form a tissue dilator to be inserted through an incision made through the pericardium to facilitate advancement of the suction pad into the pericardial space,

the suction tool body further comprising a suction lumen extending from a proximal suction fitting adapted to be coupled to a vacuum source and to the plurality of suction ports suction through which suction is applied to the pericardium to draw a pericardial bleb of the pericardium into the suction cavity when the suction cavity wall is applied against the pericardium and through which suction is applied to the epicardium to draw an myocardial bleb of the myocardium into the suction cavity when the suction pad is inserted through an incision of the pericardium into the suction cavity wall and applied against the epicardium, and a working lumen extending between a working lumen proximal end opening and an working lumen distal end opening into the suction cavity; and  
a cutting instrument having a cutting element adapted to be inserted through the working lumen for cutting into the pericardial bleb to form a pericardial incision through which the suction pad can be inserted into the pericardial space,  
whereby a cardiac lead having a distal electrode and a lead fixation mechanism for maintaining the distal electrode in contact with the myocardium can be inserted through the working lumen to fix the distal electrode in contact with the myocardium.

9. The system of Claim 8, wherein the suction tool further comprises:

a light conducting pipe extending between a light conducting pipe proximal end adapted to be coupled to a light source outside the patient's body and a light emitting distal end at the suction pad located to provide illumination about the suction pad; and  
an image conducting pipe extending between an image conducting pipe proximal end adapted to be coupled to an image capturing camera and image display outside the patient's body and an image conducting pipe at the suction pad to image the pericardium or epicardium adjacent the suction pad.

10. The system of Claim 8, wherein the suction tool further comprises:

a light conducting pipe extending between a light conducting pipe proximal end adapted to be coupled to a light source outside the patient's body and a light emitting distal end at the suction cavity wall located to provide illumination about the suction cavity wall; and  
an image conducting pipe extending between an image conducting pipe proximal end adapted to be coupled to an image capturing camera and image display outside the patient's body and

an image conducting pipe at the suction cavity wall to image the pericardium or epicardium adjacent the suction cavity wall.

11. The system of Claim 8, wherein the suction tool further comprises:  
a light conducting pipe extending between a light conducting pipe proximal end adapted to be coupled to a light source outside the patient's body and a light emitting distal end adjacent the tissue dilator to provide illumination about the suction pad distal end; and  
an image conducting pipe extending between an image conducting pipe proximal end adapted to be coupled to an image capturing camera and image display outside the patient's body and  
an image conducting pipe adjacent the tissue dilator to image the pericardium or epicardium adjacent the suction pad distal end.

12. The system of Claim 8, wherein the suction tool further comprises:  
means for providing illumination of the pericardium or epicardium adjacent the suction pad;  
and  
means for providing an image of the illuminated pericardium or epicardium adjacent the suction pad.

13. The system of Claim 8, wherein the suction tool further comprises:  
means for providing illumination of the pericardium or epicardium adjacent the suction cavity wall; and  
means for providing an image of the illuminated pericardium or epicardium adjacent the suction cavity wall.

14. The system of Claim 8, wherein the suction tool further comprises:  
means for providing illumination of the pericardium or epicardium adjacent the tissue dilator to provide illumination about the suction pad distal end; and  
means for providing an image of the illuminated pericardium or epicardium adjacent the tissue dilator to image tissue adjacent the suction pad distal end.

15. A method of accessing the epicardium of the heart through an incision through the pericardium and into the pericardial space to implant an epicardial cardiac lead comprising: inserting a suction tool body extending between a suction tool body proximal end and a suction tool body distal end through a pathway in the body to dispose a suction pad of the suction tool in proximity to the epicardium, the suction pad extending between a suction pad proximal end and a suction pad distal end, the suction pad proximal end attached to the suction tool body distal end, the suction pad shaped to have a suction cavity adapted to be applied against tissue, the suction cavity defined by an elongated, substantially concave suction cavity wall bounded by a suction cavity rim, a plurality of suction ports extending through the suction cavity wall to a suction lumen extending through the suction tool body to the suction tool body proximal end, and a working lumen extending from the suction tool proximal end into the suction cavity;

applying the suction cavity against the pericardium;

applying suction through the suction lumen and the suction ports to the pericardium to draw a pericardial bleb of the pericardium into the suction cavity;

advancing a cutting instrument through the working lumen and cutting through the pericardial bleb to form a pericardial incision;

advancing the suction pad through the pericardial incision to dispose the suction cavity against the epicardium;

applying suction through the suction lumen and the suction ports to the epicardium to draw an myocardial bleb of the myocardium into the suction cavity;

advancing a cardiac lead having a distal fixation mechanism through the working lumen; and

fixing the distal fixation mechanism to the myocardial bleb.

16. The method of Claim 15, wherein:

the step of applying the suction cavity against the pericardium comprises illuminating the pericardium and imaging the illuminated pericardium to facilitate the application of the suction cavity against the pericardium; and

the step of advancing the suction pad through the pericardial incision to dispose the suction cavity against the epicardium comprises illuminating the pericardial space and imaging the

illuminated pericardial space to facilitate the application of the suction cavity against the epicardium.

17. The method of Claim 15, wherein:

the suction tool inserted in the inserting step comprises a light conducting pipe extending between a light conducting pipe proximal end adapted to be coupled to a light source outside the patient's body and a light emitting distal end at the suction pad located to provide illumination about the suction pad, and an image conducting pipe extending between an image conducting pipe proximal end adapted to be coupled to an image capturing camera and image display outside the patient's body and an image conducting pipe at the suction pad to image the pericardium or epicardium adjacent the suction pad; and

the step of applying the suction cavity against the pericardium comprises illuminating the pericardium through the light conducting pipe and imaging the illuminated pericardium through the image conducting pipe to facilitate the application of the suction cavity against the pericardium; and

the step of advancing the suction pad through the pericardial incision to dispose the suction cavity against the epicardium comprises illuminating the pericardial space through the light conducting pipe and imaging the illuminated pericardial space through the image conducting pipe to facilitate the application of the suction cavity against the epicardium.

18. The method of Claim 15, wherein:

the step of advancing a cardiac lead having a distal fixation mechanism through the working lumen comprises:

restraining the distal fixation mechanism within a lead installation tool adjacent a tool distal end;

advancing the lead installation tool through the working lumen;

forming a proximal epicardial perforation of the myocardial bleb with the tool distal end;

advancing the tool distal end through the myocardial bleb; and

forming a distal epicardial perforation of the myocardial bleb with the tool distal end; and

the step of fixing the distal fixation mechanism to the myocardial bleb comprises:



releasing the distal fixation mechanism from the tool distal end to bear against the epicardium;

releasing the suction of the epicardium; and

withdrawing the lead installation tool and the suction tool from the cardiac lead.

19. The method of Claim 15, wherein the cardiac lead comprises a lead body bearing a pace/sense electrode and a fixation helix, and the step of fixing the distal fixation mechanism to the myocardial bleb comprises:

rotating the lead body to screw the fixation helix through the epicardium and into the myocardium;

releasing the suction of the epicardium; and

withdrawing the suction tool from the cardiac lead.

20. A method of implanting an epicardial cardiac lead comprising:

inserting a suction tool body extending between a suction tool body proximal end and a suction tool body distal end through a pathway in the body to dispose a suction pad of the suction tool in proximity to the epicardium, the suction pad extending between a suction pad proximal end and a suction pad distal end, the suction pad proximal end attached to the suction tool body distal end, the suction pad shaped to have a suction cavity adapted to be applied against tissue, the suction cavity defined by an elongated, substantially concave suction cavity wall bounded by a suction cavity rim, a plurality of suction ports extending through the suction cavity wall to a suction lumen extending through the suction tool body to the suction tool body proximal end, and a working lumen extending from the suction tool proximal end into the suction cavity;

forming a pericardial incision;

advancing the suction pad through the pericardial incision to dispose the suction cavity against the epicardium;

applying suction through the suction lumen and the suction ports to the epicardium to draw an myocardial bleb of the myocardium into the suction cavity;

advancing a cardiac lead having a distal fixation mechanism through the working lumen; and fixing the distal fixation mechanism to the myocardial bleb.

21. The method of Claim 20, wherein the step of advancing the suction pad through the pericardial incision to dispose the suction cavity against the epicardium comprises illuminating the pericardial space and imaging the illuminated pericardial space to facilitate the application of the suction cavity against the epicardium.

22. The method of Claim 20, wherein:  
the suction tool inserted in the inserting step comprises a light conducting pipe extending between a light conducting pipe proximal end adapted to be coupled to a light source outside the patient's body and a light emitting distal end at the suction pad located to provide illumination about the suction pad, and an image conducting pipe extending between an image conducting pipe proximal end adapted to be coupled to an image capturing camera and image display outside the patient's body and an image conducting pipe at the suction pad to image the pericardium or epicardium adjacent the suction pad; and  
the step of advancing the suction pad through the pericardial incision to dispose the suction cavity against the epicardium comprises illuminating the pericardial space through the light conducting pipe and imaging the illuminated pericardial space through the image conducting pipe to facilitate the application of the suction cavity against the epicardium.

23. The method of Claim 20, wherein:  
the step of advancing a cardiac lead having a distal fixation mechanism through the working lumen comprises:  
restraining the distal fixation mechanism within a lead installation tool adjacent a tool distal end;  
advancing the lead installation tool through the working lumen;  
forming a proximal epicardial perforation of the myocardial bleb with the tool distal end;  
advancing the tool distal end through the myocardial bleb; and  
forming a distal epicardial perforation of the myocardial bleb with the tool distal end; and  
the step of fixing the distal fixation mechanism to the myocardial bleb comprises:  
releasing the distal fixation mechanism from the tool distal end to bear against the epicardium;

releasing the suction of the epicardium; and  
withdrawing the lead installation tool and the suction tool from the cardiac lead.

24. The method of Claim 20, wherein the cardiac lead comprises a lead body bearing a pace/sense electrode and a fixation helix, and the step of fixing the distal fixation mechanism to the myocardial bleb comprises:

rotating the lead body to screw the fixation helix through the epicardium and into the myocardium;

releasing the suction of the epicardium; and  
withdrawing the suction tool from the cardiac lead.

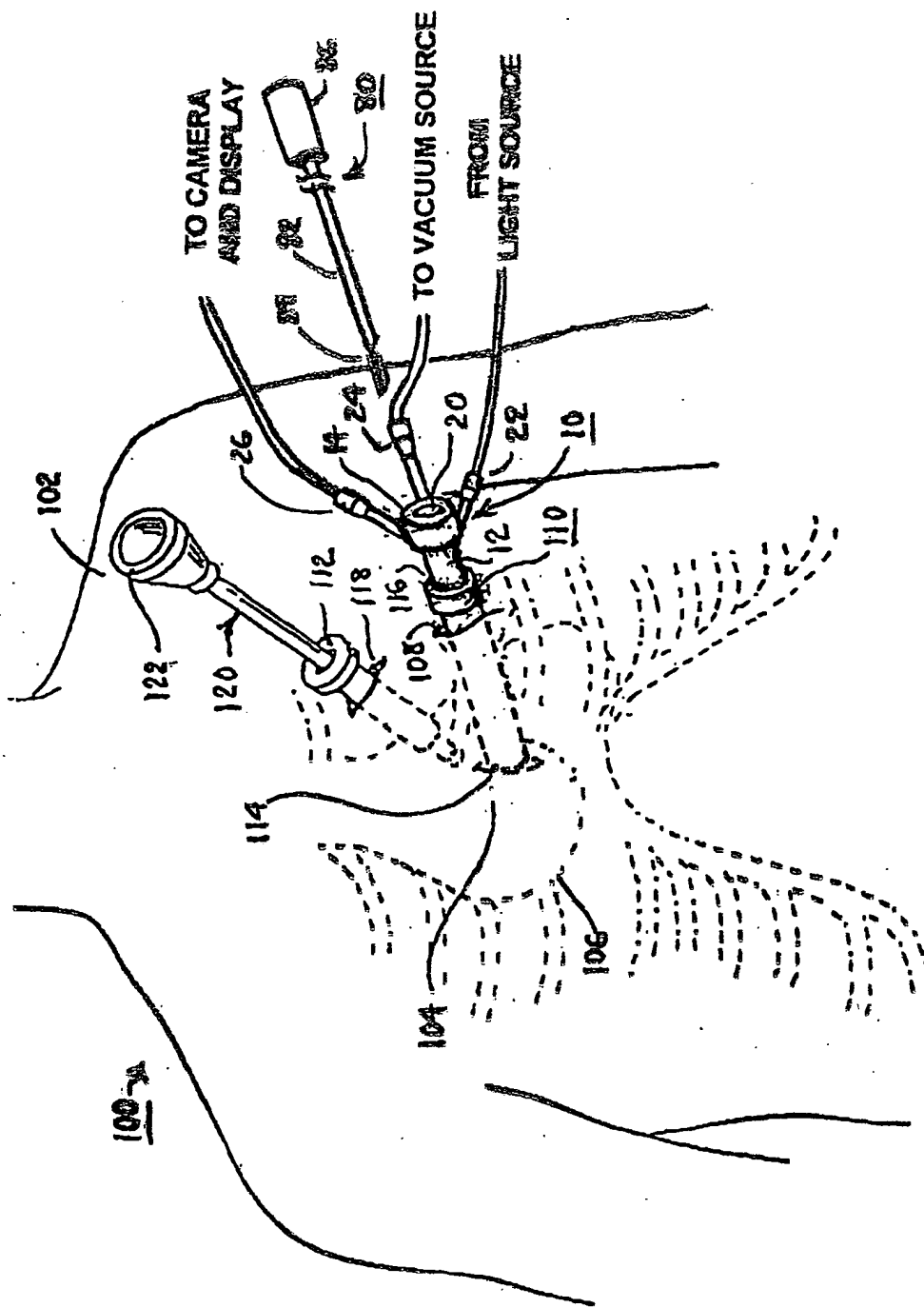
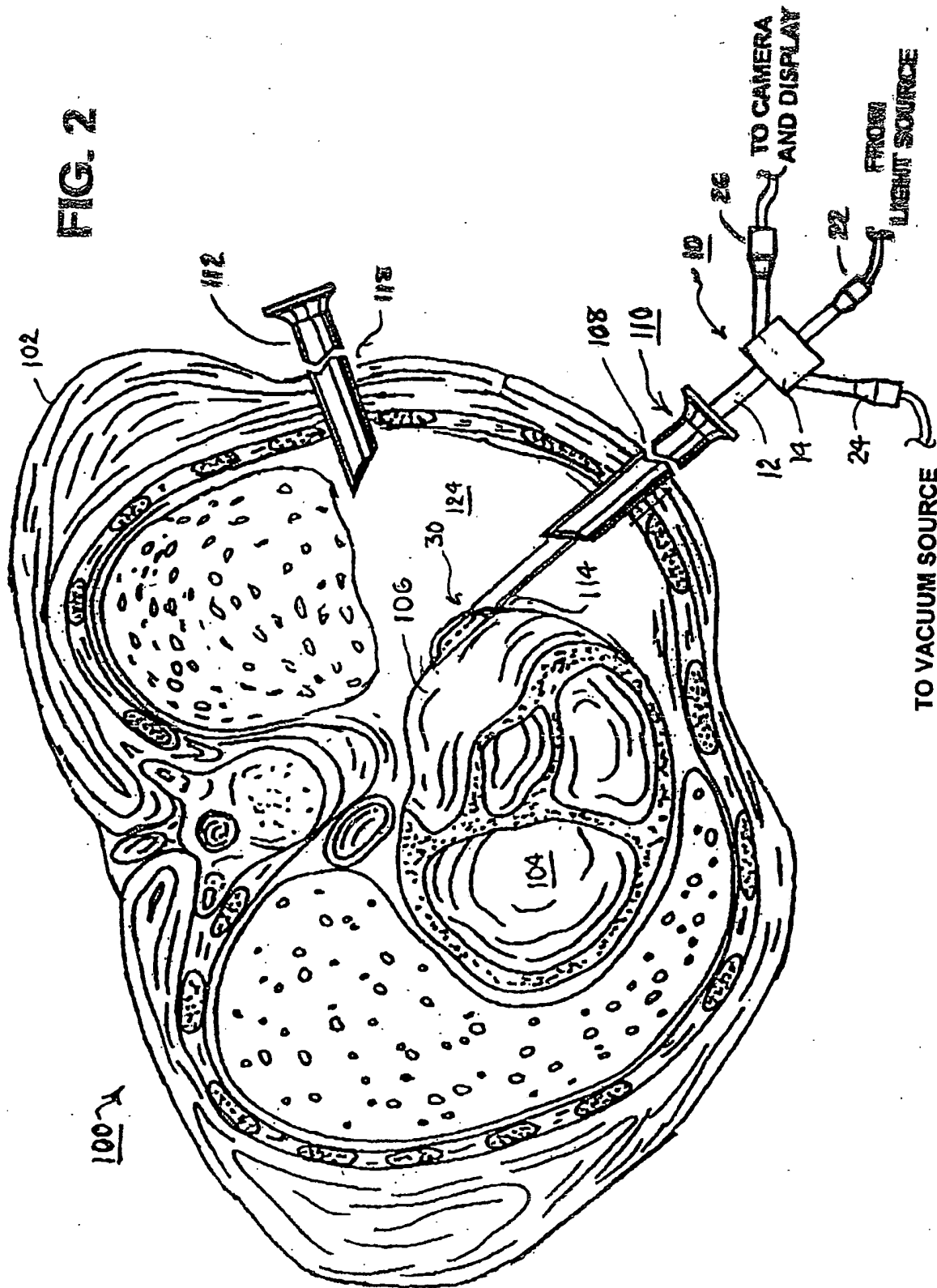


FIG. 1

FIG. 2



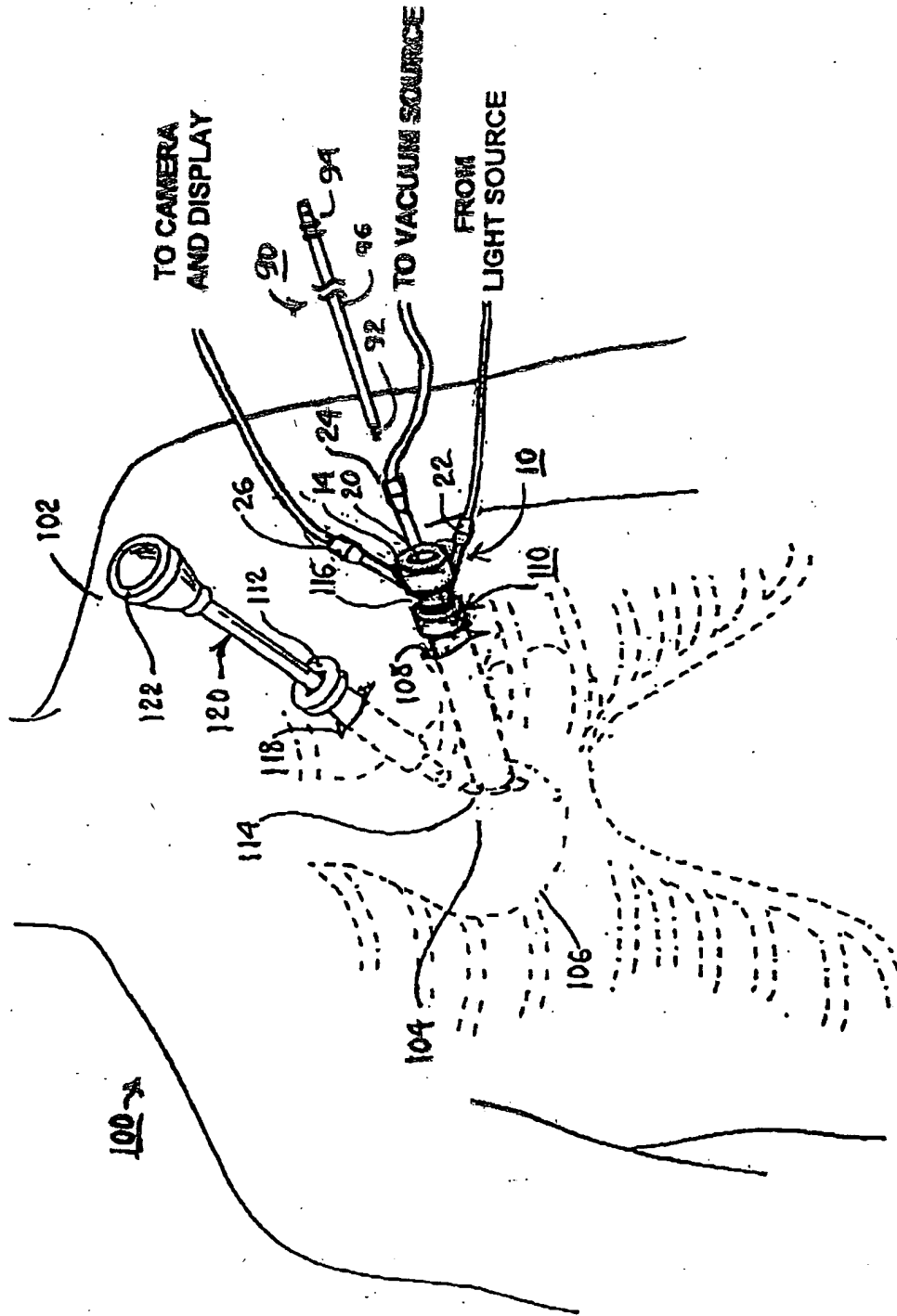


FIG. 3

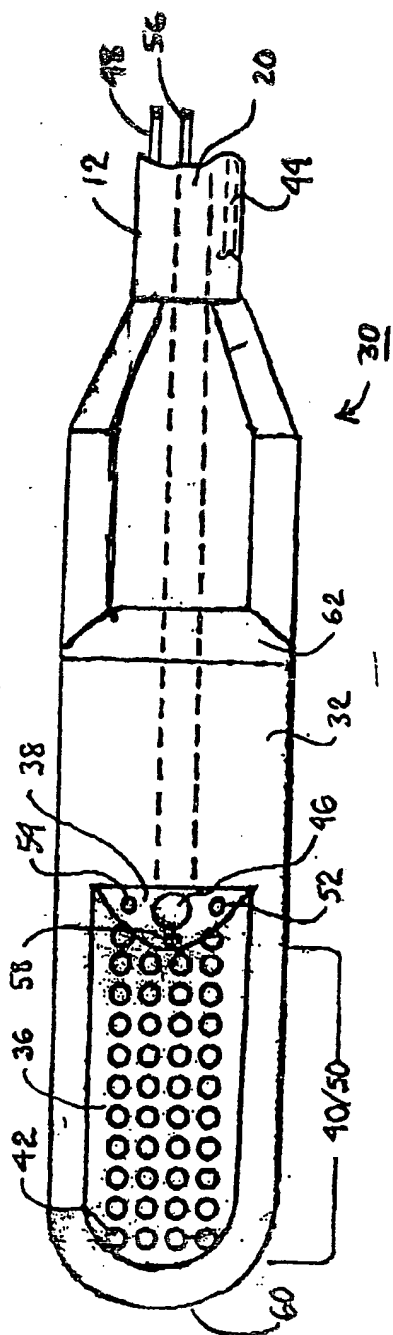


FIG. 4

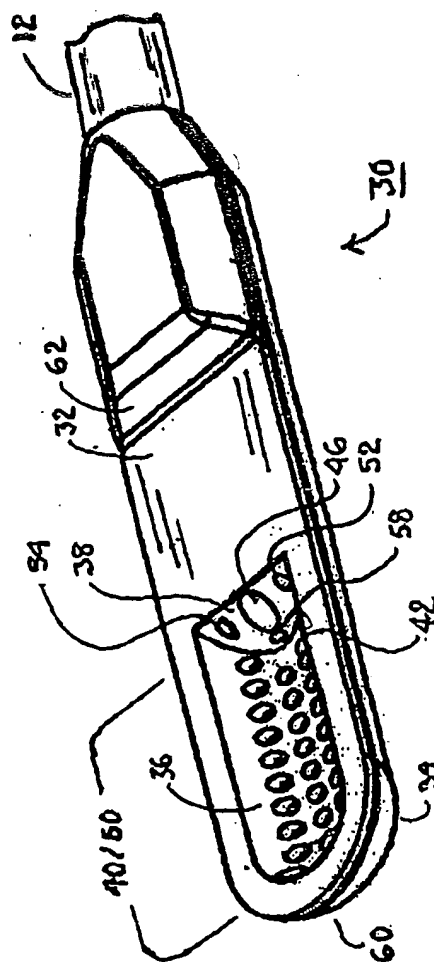
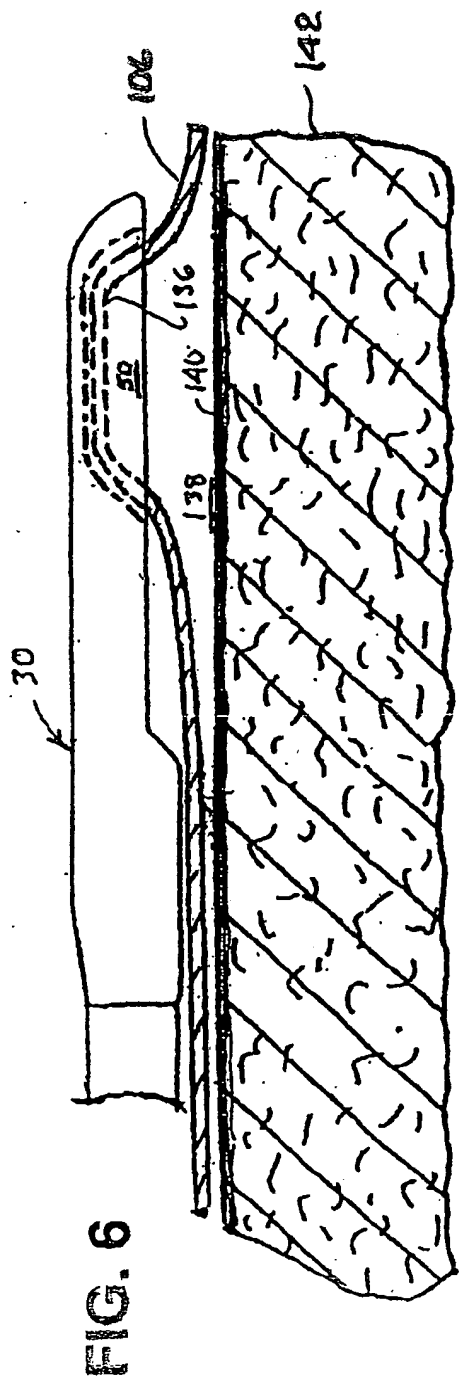
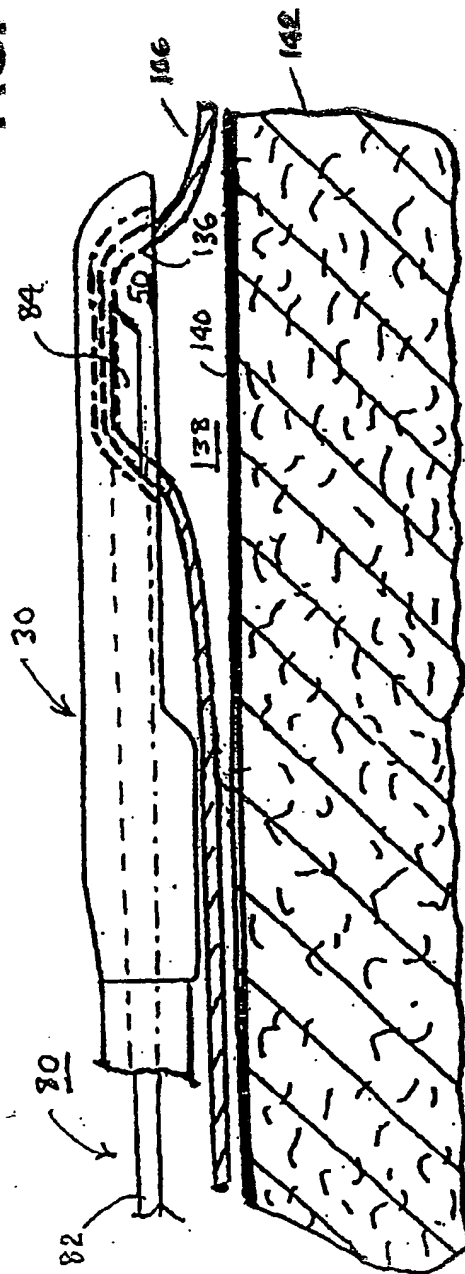


FIG. 5



**FIG. 7**





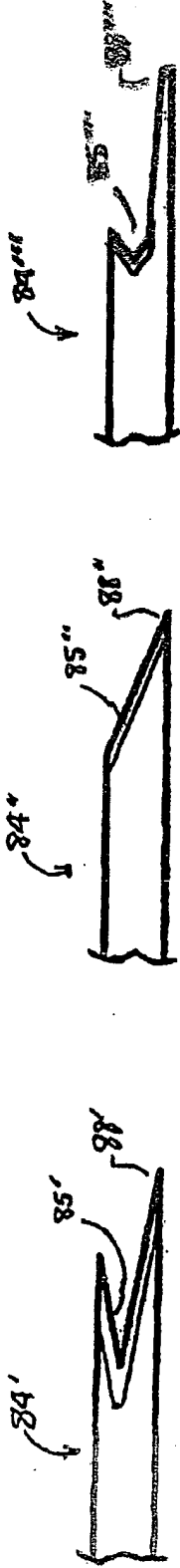


FIG. 15

FIG. 16

FIG. 17

FIG. 8

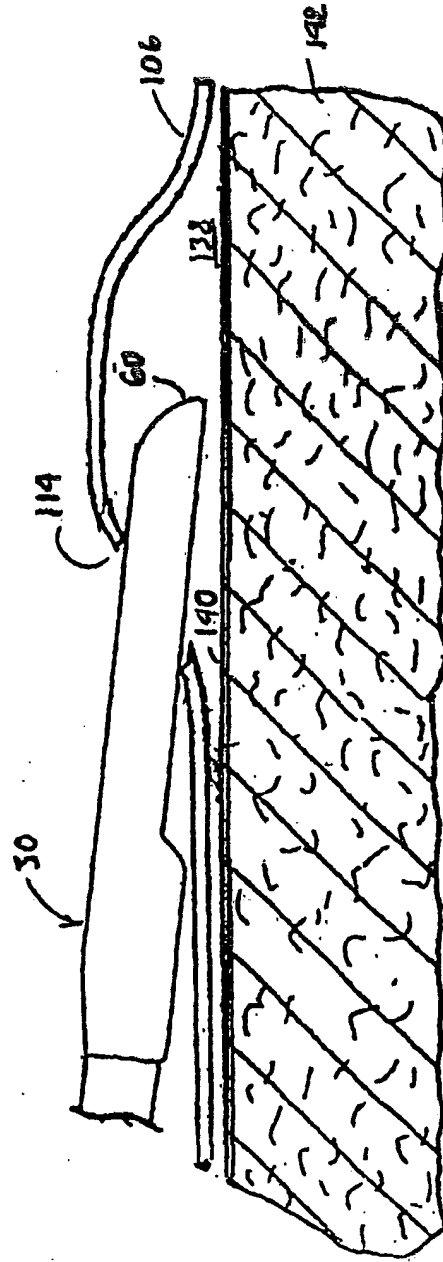


FIG. 9

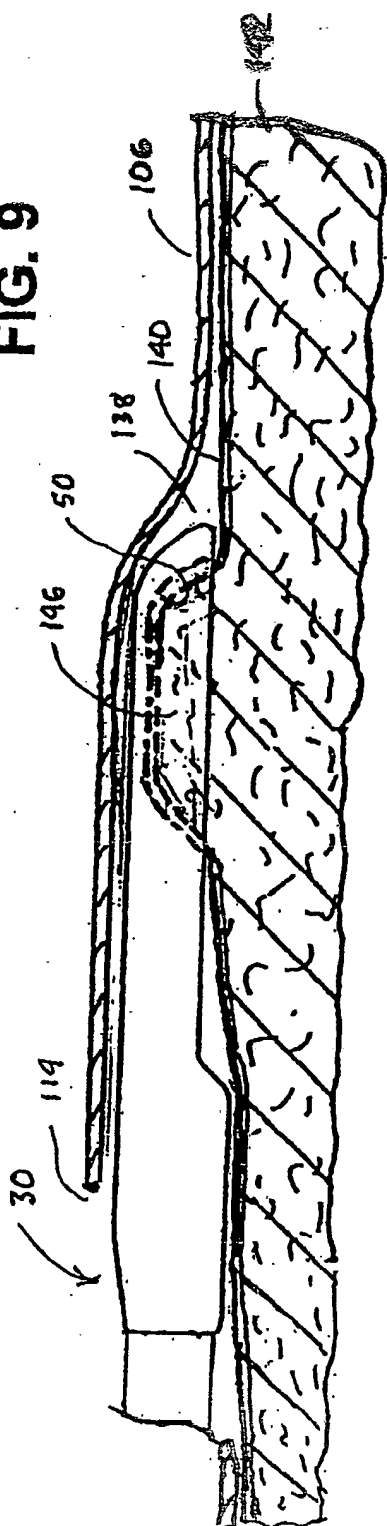


FIG. 10

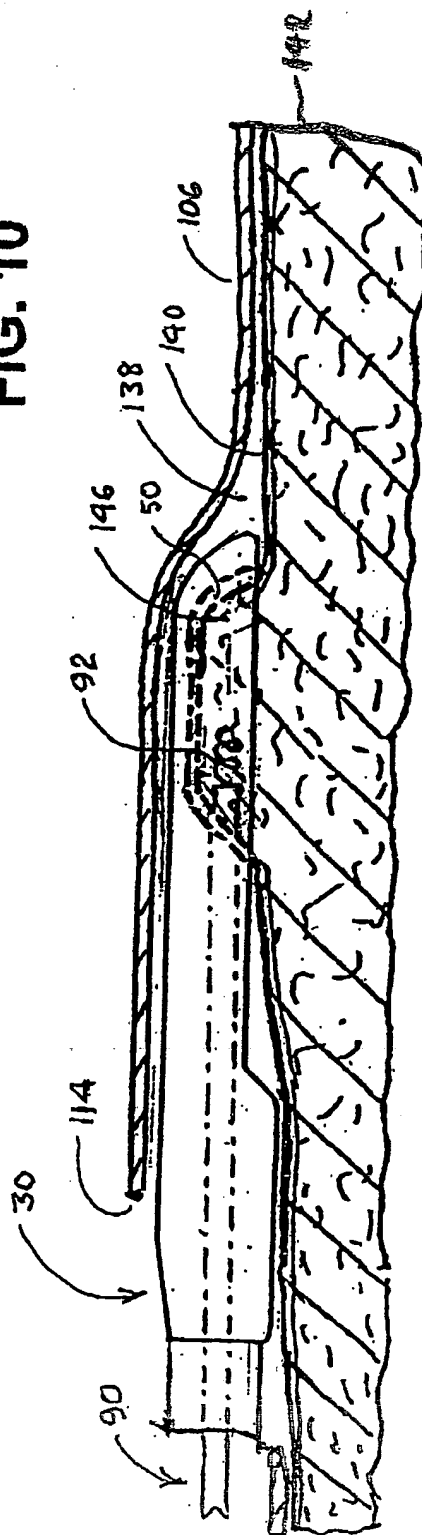


FIG. 11

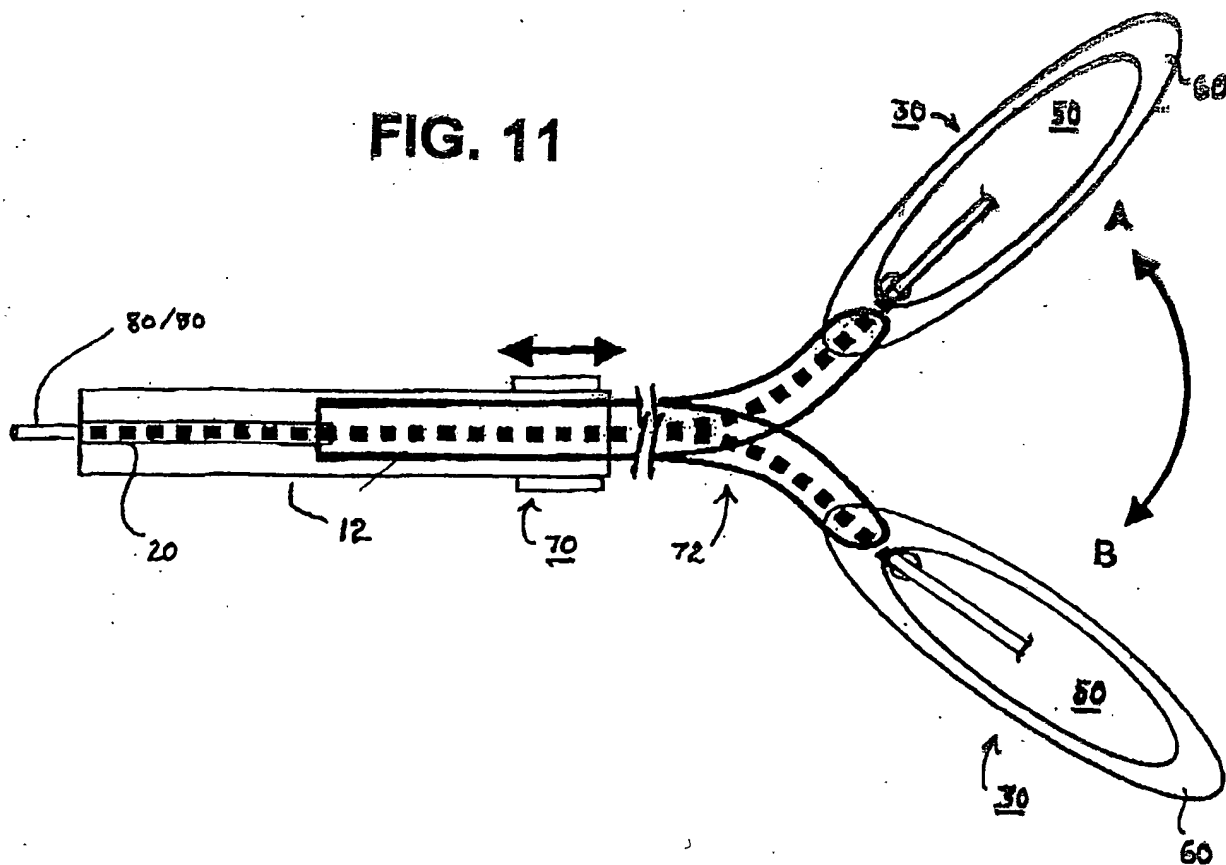


FIG. 12A

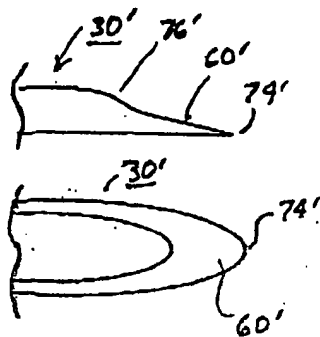


FIG. 12B

FIG. 13A

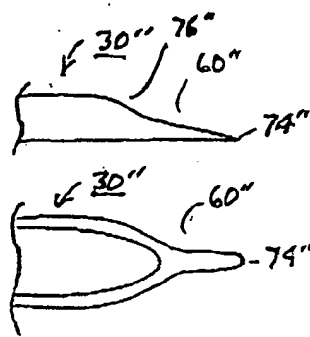


FIG. 13B

FIG. 14A

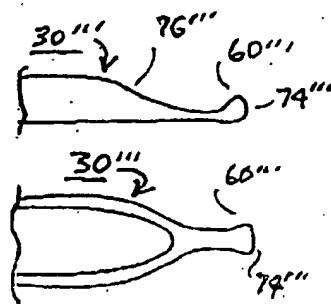


FIG. 14B

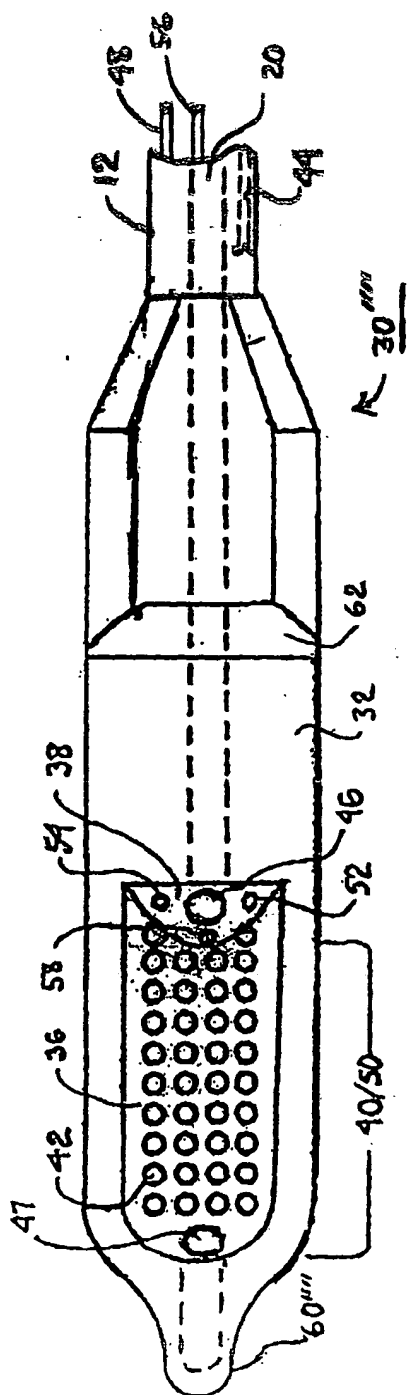


FIG. 18

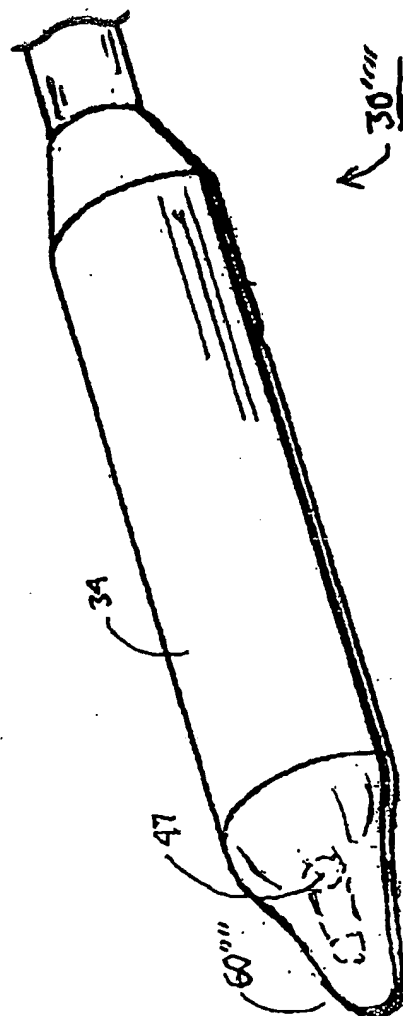
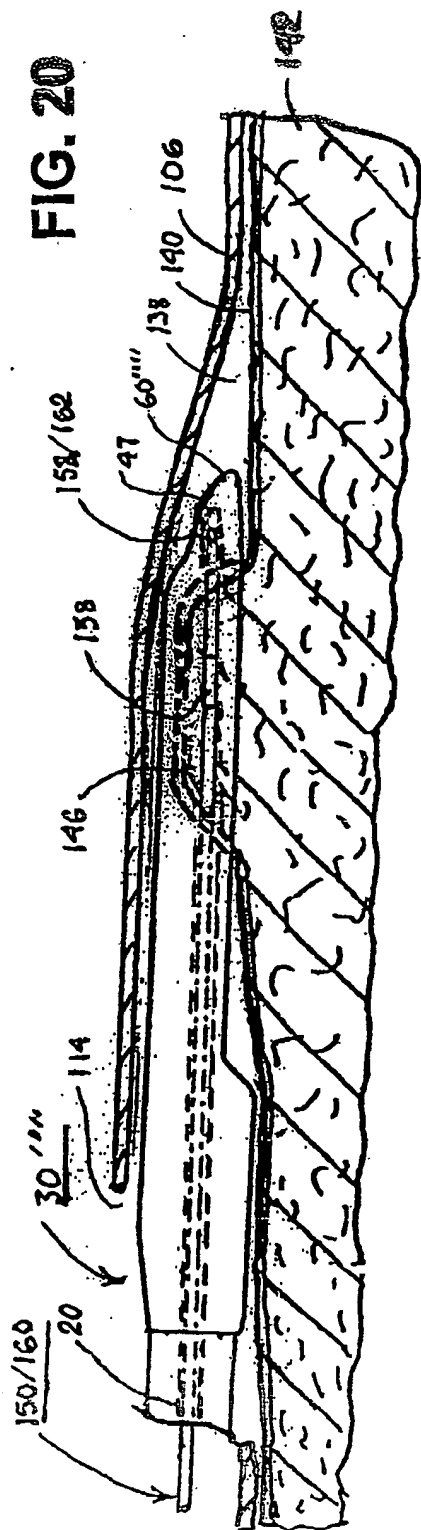
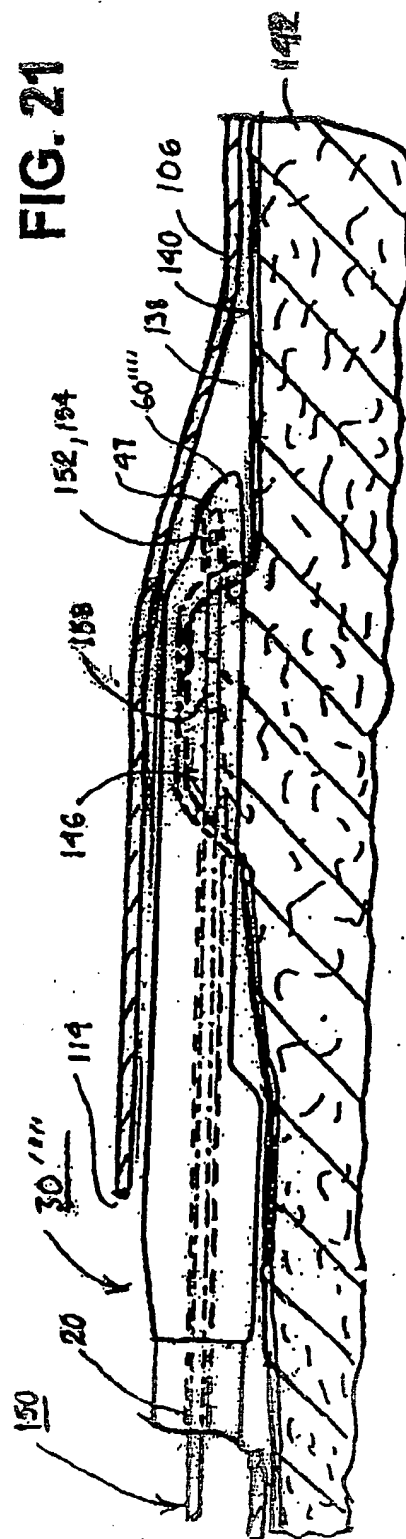


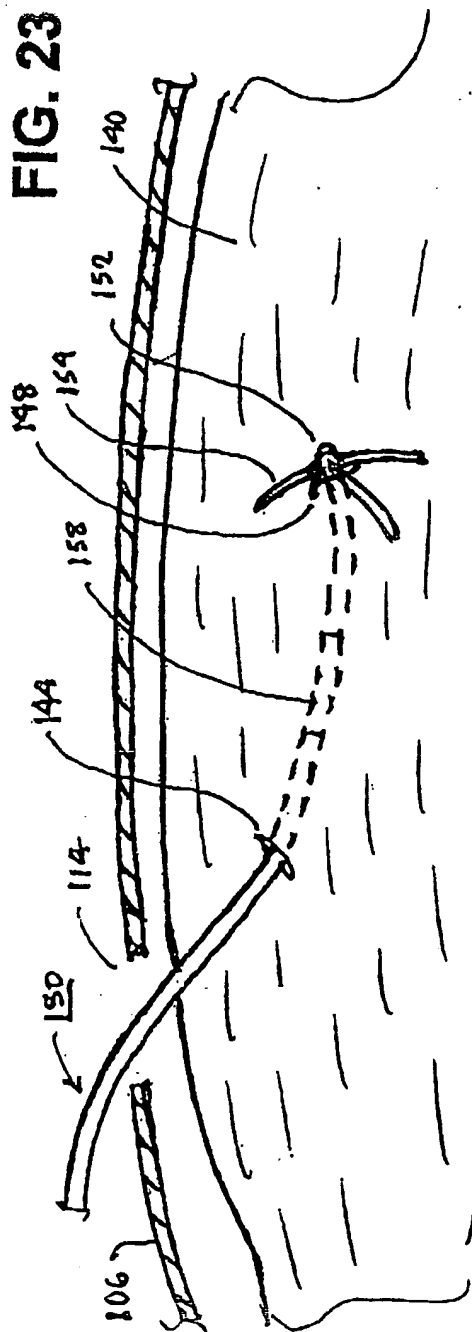
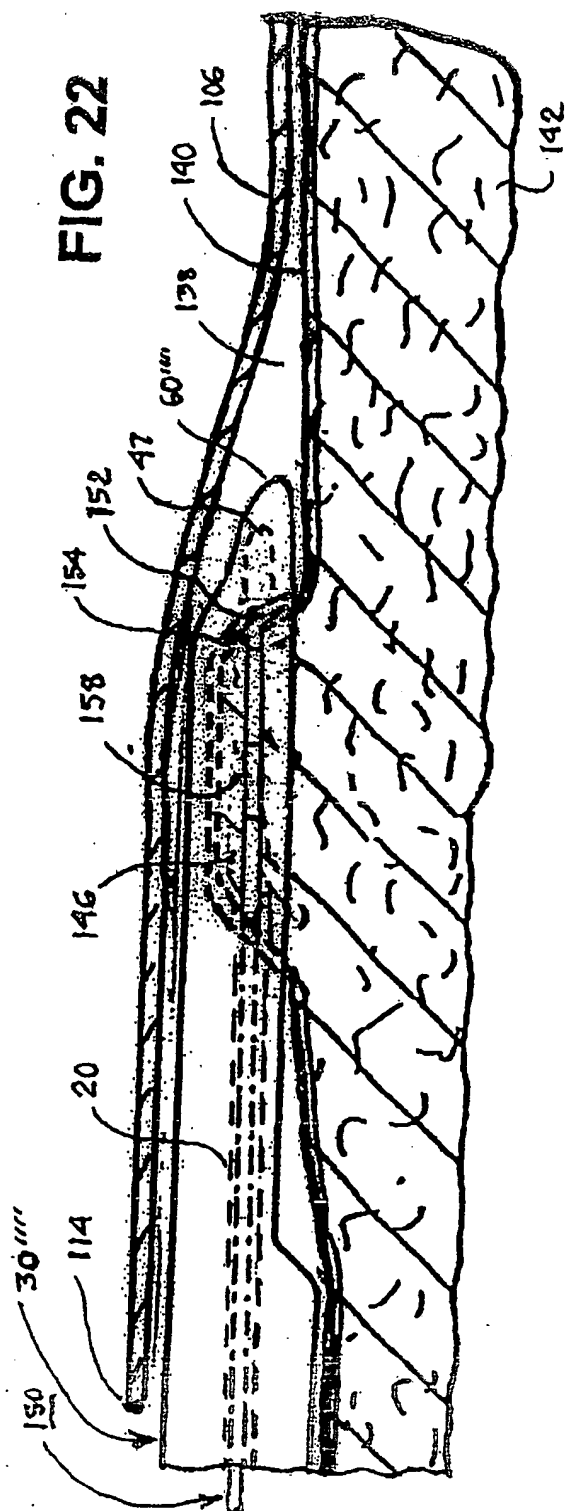
FIG. 19

FIG. 20



**216**





## INTERNATIONAL SEARCH REPORT

International Application No.  
PCT/US2004/000597

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 A61B17/02

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6 231 518 B1 (RIEGER PATRICIA J ET AL) 15 May 2001 (2001-05-15) column 5, line 1 -column 6, line 27; figures 3-8	1-14
Y	US 6 478 728 B1 (WRIGHT JOHN T M) 12 November 2002 (2002-11-12) figures column 2, line 55 - line 65	1
Y	WO 00/74574 A (MEDIVAS LLC) 14 December 2000 (2000-12-14) page 17, line 26 -page 18, line 11 figures	1-14

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*Z\* document member of the same patent family

Date of the actual completion of the international search

7 June 2004

Date of mailing of the international search report

23/06/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Held, G

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2004/000597

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6 162 195 A (IGO STEPHEN R ET AL) 19 December 2000 (2000-12-19) figures column 6, line 28 -column 7, line 7	1-14
Y	US 5 396 252 A (COHEN DONALD M) 9 August 1994 (1994-08-09) column 11, line 30 - line 34 column 12, line 16 - line 44 column 13, line 12 -column 14, line 32 figures	1-14



# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2004/000597

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6231518	B1	15-05-2001	AU 762622 B2 03-07-2003
		AU 4206699 A	13-12-1999
		CA 2333149 A1	02-12-1999
		EP 1082052 A1	14-03-2001
		JP 2002516134 T	04-06-2002
		WO 9960924 A1	02-12-1999
US 6478728	B1	12-11-2002	NONE
WO 0074574	A	14-12-2000	US 6231585 B1 15-05-2001
		CA 2375305 A1	14-12-2000
		EP 1189538 A1	27-03-2002
		JP 2003501130 T	14-01-2003
		WO 0074574 A1	14-12-2000
US 6162195	A	19-12-2000	US 5827216 A 27-10-1998
		US 6666844 B1	23-12-2003
		AU 6179996 A	30-12-1996
		CA 2223954 A1	19-12-1996
		EP 0956094 A1	17-11-1999
		JP 2001506869 T	29-05-2001
		WO 9640368 A1	19-12-1996
US 5336252	A	09-08-1994	NONE

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2004/000597

## Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 15-24  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(1v) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest:

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**